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Thea L. Urban
Certified Shorthand Reporter
134 South LaSalle Street
Chicago, Illinois 60603
312-782-3332

18 June 1982

Mr. Bruce A. Featherstone
Kirkland & Ellis
200 East Randolph Drive
Chicago, Illinois 60601

Re: Case No. 78 C 1004 - USA vs. OMC and Monsanto Company
Deposition of Dr. William R. Gaffey

Dear Bruce:

Enclosed is your copy and the original transcript of Dr. William Gaffey's testimony, taken in the above-entitled cause on June 3, 1982 at your offices.

I appreciate your help in submitting the original to the deponent for reading and signing.

Sincerely,

Thea L. Urban

TLU/bm
Enc.

cc Ms. Elizabeth Stein ✓
Mr. James T. Hynes
Mr. Richard T. Phelan
Ms. Roseann Oliver
File

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 78 C 1004
	)	
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
	)	
	)	
Defendants.	)	

The deposition of DR. WILLIAM R. GAFFEY, called by the Plaintiff for examination, pursuant to notice and agreement and pursuant to the Rules of Civil Procedure for the United States District Courts pertaining to the taking of depositions, taken before Thea L. Urban, a Notary Public in and for the County of Cook, State of Illinois, and a Certified Shorthand Reporter of said State, at the offices of Kirkland & Ellis, 200 East Randolph Drive, Chicago, Illinois 60601, on the 3rd day of June, A.D. 1982, commencing at 10:00 o'clock a.m.

PRESENT:

MS. ELIZABETH STEIN,
(Pollution Control Section
Land & Natural Resources Division
Department of Justice
Washington, D.C. 20530),

appeared on behalf of the
United States of America;

16-5V28.0|077

PRESENT: (Cont'd.)

MR. RICHARD T. PHELAN and
MS. ROSEANN OLIVER,
(Phelan, Pope & John, Ltd.
30 North LaSalle Street
Chicago, Illinois 60602),

appeared on behalf of Outboard Marine Corporation;

MR. BRUCE A. FEATHERSTONE,
(Kirkland & Ellis
200 East Randolph Drive
Chicago, Illinois 60601),

appeared on behalf of Monsanto Company.

ALSO PRESENT:

MR. MARK FERGUSON.

- - -

I N D E X

E X H I B I T S

CERTIFIED QUESTIONS

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(Witness sworn.)

WILLIAM R. GAFFEY,

called as a witness herein, having been first duly sworn, was examined and testified as follows:

DIRECT EXAMINATION

BY MS. STEIN:

Q State your name, please.

A William R. Gaffey.

Q What is your business address?

A 800 North Lindbergh Boulevard, St. Louis, Missouri 63167.

MS. STEIN: Let the record reflect this is a deposition pursuant to notice, agreement of the parties and Federal Rules of Civil Procedure.

BY MS. STEIN:

Q Dr. Gaffey, what is your home address, please?

A My home address is 11269 Pineside Drive, St. Louis, Missouri 63141.

Q Your occupation?

A I am Manager of Epidemiology, Monsanto Company.

Q When did you begin as Manager of Epidemiology for the Monsanto Company?

A In July of 1979.

Q Could you briefly state your educational

background?

A I have a Bachelor's Degree in Psychology and a Ph.D. in Mathematical Statistics, both from the University of California at Berkeley.

Q Is your current curriculum vitae up to date?

A Let me examine the list of publications. Yes.

(Gaffey-USA Deposition Exhibit No. 1 marked for identification, 6/3/82,TLU.)

Q You received your Bachelor's Degree in Psychology in 1948, is that correct?

A That is correct.

Q The Ph.D. in Mathematical Statistics in 1955, is that correct?

A That is correct.

Q What did you do between 1948 and 1955?

A I was a graduate student and part-time research assistant and teaching assistant, both in the Department of Statistics and at the School of Public Health, also at the University of California.

Q Were you teaching courses during that time?

A Yes.

Q What were you teaching?

A My teachings were in the Division of Biostatistics in the School of Public Health.

I taught an elementary course in statistics

for graduate students in the Master's curriculum in that department and taught both senior level and graduate level courses in Applied Statistics to undergraduate and graduate students in Biostatistics.

I also conducted research and did some consultation.

Q Could you explain what the discipline of biostatistics is, please?

A Biostatistics is the branch of applied statistics that concerns itself with data in the life sciences from epidemiology and from public health.

Q What was the research that you did during the period 1948 to 1955?

A It varied and the publications are listed in my CV, but it consisted of two kinds of general research. One was into theoretical statistics. The other was research and collaboration with researches in the Department of Physiology involving dietary experiments in animals and I also did some research on trends in public health statistics such as the stillbirth rate.

Q With respect to your research in theoretical statistics, were you developing models or what were you doing?

A I developed a method for compensating for

instrumental error which creeps into measurements of complicated chemical and other processes.

Q Were there specific instruments that you --

A No.

MR. FEATHERSTONE: Dr. Gaffey, wait until she finishes the question.

BY MS. STEIN:

Q Were there specific instruments that you employed in developing this method for compensating for instrument error?

A No.

Q Was it a general method of some sort?

A It was a general statistical method.

Q Would you describe this general statistical method for compensating for instrument error?

A It is a rather technical and complicated procedure, but essentially it involved making calculations on observed data, combining this with knowledge of the type of probabilities of errors that existed in instruments and using the combination of these two sources of information to estimate the nature of the underlying data.

Q Did a publication result from that work?

A Yes.

Q Is that listed on your CV?

A Yes, it is.

Q Which one is that?

A It is the third one, A Consistent Estimator of a Component of a Convolution.

Q Are you familiar with the concept of peer review in the scientific community?

A Yes.

Q Could you give me your definition of peer review?

A A peer review is a review of a scientific work by a qualified person who is employed in the same area and the same specialty.

Peer review is usually done anonymously so as to guarantee the impartiality of the review.

Q Was your publication A Consistent Estimator of a Component of a Convolution a peer review document?

A Yes.

Q With regard to your research in trends and Public Health statistics such as stillbirth rate, were there other trends that you examined as well?

A Do you mean in that particular piece of research?

Q That is correct.

A No.

Q During the period 1948 to 1955, did you do other examinations of trends in Public Health statistics, other than the stillbirth rate?

A Not that I recall.

Q Did the research that you did on trends in Public Health statistics such as stillbirth statistics result in a publication?

A No, it did not.

Q What happened to it?

A I gave the paper at a meeting of the American Health Association and did not further pursue the issue of publishing it.

Q Do you recall what year that was?

A It would have been somewhere between 1955 and 1958.

Q Does the American Public Health Association publish its proceedings?

A Not necessarily. Some papers read there subsequently are published; not all.

Q In connection with your work toward a Ph.D. did you prepare a dissertation?

A Yes, I did.

Q What was the topic of your dissertation?

A The Problem of Within Family Contagion.

Q Was there a particular hypothesis with which you started?

A No. It was an attempt to construct a mathematical goal.

Q Were you able to do so?

A Yes.

Q During the time that you were Assistant Professor of Biostatistics, University of California School of Public Health, what were the courses that you taught?

MR. FEATHERSTONE: Didn't you already answer that, Doctor?

THE WITNESS: I beg pardon?

MR. FEATHERSTONE: Didn't you already answer that?

THE WITNESS: I believe I have in my statement about basic courses for Master Degrees and again in dates, undergraduate and graduate courses in Biostatistics.

MS. STEIN: I recall that I asked that question with regard to the time period between 1948 and 1955.

BY MS. STEIN:

Q Is your answer different if that is the time frame?

A Oh, different in the sense that as Assistant Professor, I taugnt a larger number of graduate courses.

Q What did you do as a statistical consultant for the California State Department of Public Health?

A That position was a full-time position with the California State Department of Public Health in which I provided statistical and biostatistical consultation to the various research projects that were then in progress within the department.

Q Do you recall whether any of those projects in progress at the time you were at California State Department of Public Health involved halogenated hydrocarbons?

A To the best of my recollection, they did not.

Q Then your next job was as Chief, Bureau of Statistical Services for the California State Department of Public Health, is that correct?

A That is correct.

Q During that time, would you describe the duties that you performed?

A I was supervisor in a technical sense of the group of statisticians that were employed by the California Department of Health, both in their research projects and in their regular program activities.

Q Can you describe what you mean by supervisor in a technical sense?

A I mean that I was the person who supervised the type of statistics that were gathered and who approved the type of research protocols that were proposed.

Q Were there standards for evaluating the research protocols that were used during the time that you were the Chief of the Bureau of Statistical Services?

A Do you mean written standards?

Q Right.

A No.

Q By written standards, I am not limiting it to some that may have been published by the State of California.

Were there any others?

A These proposals were reviewed in light of what would be accepted as sound scientific procedure.

Q In terms of evaluating these projects and the research protocols, what are the criteria that were factored into whether or not something fell within the generally accepted sound scientific procedures?

A First, a clear statement of the hypothesis to be tested; second, a clear statement of data to be collected and the precautions to be taken to ensure accuracy and lack of bias, and third, a clear statement of

the type of analysis that was to be done and the utility of the investigation to the mission of the department.

Q What were the precautions that were looked for in evaluating these projects and protocols to guard against bias in the data?

A Some of them were technical procedures such as duplicate independent coding of data. Some were reviews of the type of questionnaires that were to be used and the pretesting of these to guarantee their effectiveness.

Q Anything else?

A Sometimes we called outside consultants to give us information on types of confounding variables that we should be wary of.

Q Were the confounding variables that you looked for project specific or general?

A Both.

Q Could you give me an example?

MR. FEATHERSTONE: Of which?

BY MS. STEIN:

Q Project specific and confounding variables first.

A In a project in which we inquired of people

about their past health experience, we were concerned that people who were queried by telephone might give consistently different answers from those that were interviewed personally. This sort of bias was investigated by a pretest.

Q Did you find out whether there was a difference in responses?

A There was no difference except on two or three specific questionnaire areas.

Q What were those areas?

A Race and consumption of alcohol.

Q Could you give me some examples of general confounding variables?

A Race and sex.

Q Any others?

A Those are the major ones that I can think of.

Q According to your curriculum vitae, you were the Chief of Bureau of Statistical Services in 1968 and 1969 and then you became Senior Biostatistical Consultant, Pacific Medical Center, 1970 and '71.

A That is correct.

Q Was there a gap there?

A No. I left the Health Department at the very end of 1969 and took up my job in the Pacific Medical

Center a matter of weeks later, at the very beginning of 1970.

Q What were your duties as a Senior Biostatistical Consultant at the Pacific Medical Center?

A To provide consultation to a research institute which consisted of a number of different projects carrying on various types of medical research.

Q What kinds of research were they engaged in?

A The development of more efficient artificial heart/lung machine was one.

Q Was Pacific Medical Center engaged in epidemiological studies?

A No, they were not.

Q Let me back up for a minute and ask you to define an epidemiological study so that we will be talking about the same thing.

A An epidemiologic study is the study of the risks of ill health in a human population related to some other factors present in that population.

Q Is there a specific definition of ill health?

A No.

Q Is that a subjective term then?

A No, it is simply that it covers a wide range of objective phenomenon.

Q What were those objective phenomenon?

A One example can be death, another can be physician-diagnosed illness. Another can be disability. Another can be self-reported illness or symptoms.

Q What do you mean by disability? Are there any specific criteria?

A Inability to carry out one's usual activities.

Q Is there some sort of a threshold measurement that is used?

A Not that I am aware of.

Q Are there criteria for evaluating what is a disability?

A There are criteria which appear to vary from study to study.

Q Are these criteria published anywhere?

A I believe they are, but I cannot give you a source for the publication.

Q Would that be in a text or would they be in published literature?

MR. FEATHERSTONE: Well, a text is published literature. Why don't you be more specific.

Do you mean in a text or in a periodical of some sort?

MS. STEIN: Tnat's fine.

BY THE WITNESS:

A I don't know.

BY MS. STEIN:

Q What are some of the criteria that you can recall? We are talking about evaluating disabilities, still.

A Certification by a physician that an individual is not physically able to perform his usual activity.

Q Do you know, is there a checklist of some sort that physicians use in making that certification?

MR. FEATHERSTONE: Objection, lack of foundation.

BY MS. STEIN:

Q You may answer, Doctor.

A I don't know.

Q What do you mean by self-reported illness or symptoms?

A If someone is given a questionnaire that asks such and so question as, "Were you ill last week," or, "What was the cause," and the answer comes from the individual himself by his own report. This is what I mean by self-reported symptom or illness.

Q And a physician-diagnosed illness, what is that? What do you mean by that?

A An opinion rendered by a physician giving

medical diagnosis for an illness.

Q Is that completely separate from a self-reported illness or symptom?

A Yes, that is.

Q How is that different?

MR. FEATHERSTONE: By definition, Elizabeth, if you listen to his definition. One comes from the patient itself. The other is diagnosed by a physician.

MS. STEIN: I am trying to figure out what the basis of the hypothesis is that the physician make the diagnosis of illness.

There must be some interplay with the patient.

MR. FEATHERSTONE: I will accept that if that is the question.

Go ahead and respond.

BY THE WITNESS:

A It would be whatever examination the physician chose to make, either in terms of inquiry, actual hands-on physical examination or what have you.

BY MS. STEIN:

Q I just realized that you had earlier said you had done some consulting work while you were in Berkeley, is that correct?

A I said that among my duties both as a graduate student and as junior faculty member was consultation.

Q For whom did you consult?

A For other departments in the University of California and for the California Department of Health Services.

Q What was the nature of some of the projects that you did while a consultant for the University of California?

A I consulted with a group of physiologists on the design and analyses of animal dietary experiments designed to stress arteriosclerosis.

I consulted with the California Department of Health Services on an analysis and writing of the report for a California Health Survey which was a pilot study that later became the National Health Survey.

Q Did you work out standards for evaluating the data in the pilot survey?

A I worked out in consultation with people in the Health Department, worked out procedures for analysis and worked out the format for the report which was going to the U.S. Public Health Services.

Q What were some of those procedures that you developed?

A The sample that was taken was a rather involved one from the point of view of statistical design and the major analytic problems were in characterizing the precision of estimates that came from that sample.

My contribution was to assist in developing the formulas for the standard deviations of proportions and means that constituted the report.

Q Can you explain what you mean with regard to your work involving standard deviations of proportions and means to constitute the report?

A The standard deviations is a standard statistical concept which is the statistics used to measure the precision of an estimate such as a mean or proportion.

Q What is a mean?

A A mean of a sample of observations is the sum of those observations divided by the number of those observations.

Q What is a proportion?

A A proportion is a number of observations in a sample that possess a certain characteristic divided by the total number of observations in the sample.

Q After you were Senior Biostatistical Consultant of the Pacific Medical Center, you became Associate Director for Human Population Laboratory for Epidemiologic

Studies for the California State Department of Public Health, is that correct?

A Yes, that is correct.

Q What did you do while the Associate Director?

A I administered a project which hired three or four behavioral scientists at the doctoral level whose main task was analyzing data from a longitudinal study of sample of people from the general population of the county in which the department was located.

My job was to provide general administration and to provide statistical consultation in the various projects which centered around analysis from the data from that longitudinal study.

Q What is a longitudinal study?

A A longitudinal study is a study that follows the same group of individuals over a period of time and takes periodic or reported measurements on the same individuals in order to determine and evaluate trends in the population.

Q And did you just work on one study during the time that you were Associate Director?

A There were a number of analyses involving data from the same sample. It is a large widespread amount of data that were collected.

Different professional members of staff performed different analyses on different parts of the data.

Q What were you looking for in that study?

A This was what is called the Hypothesis Gentract Study. We were concerned with the relationship between health and various measures of lifestyle, way of life, income, et cetera.

Q Did this study involve any kind of assessment of the risk of exposure to any particular agents in the environment?

A No, it did not.

Q I am backing up.

During the time that you were initially Senior Biostatistical Consultant to the Pacific Medical Center, did your work involve assessment of risk from environmental exposure to an agent?

A No, it did not.

Q During the time that you were Chief, Bureau of Statistical Services, did your work involve assessment of the risk of environmental exposure to any particular agents?

A Indirectly, yes.

Q Could you explain that answer, please?

A I was principal consultant on a study which measured the variation of blood pressure in a sample of individuals taken from a defined geographic area and attempted to relate blood pressure variables such as race, sex and income and identification.

Q Do you recall what the conclusions of that study were?

A Essentially that there was sex difference in blood pressure: that there was an income difference in blood pressure and that there was a rational difference in blood pressure that was not explainable by either of the preceding variables.

Q During the time that you were Statistical Consultant to the California Department of Public Health, did you assess the risk of exposure, the risk of environmental exposure to an agent?

MR. FEATHERSTONE: Is your question whether he was involved in those projects?

MS. STEIN: That's right.

BY THE WITNESS:

A No, I was not.

BY MS. STEIN:

Q During the time that you were a Professor of Biostatistics, were you involved in any work in assessing

the risks from environmental exposure to an agent?

A No, not to the best of my recollection.

Q According to your curriculum vitae, the next position you held was as Director of Health and Epidemiological Studies at Tabershaw/Cooper Associates, Inc., is that correct?

A Tabershaw/Cooper Associates, yes.

Q What is Tabershaw/Cooper Associates?

A That company was a consulting organization that provided consultation and research on a contract basis to Government and industry.

Q What kinds of areas did they provide these consulting services in?

A In epidemiology, in library research and in occupational medicine and in industrial hygiene.

Q What did you do during the time that you worked with Tabershaw/Cooper Associates?

A I designed studies and prepared proposals to clients to conduct such studies; supervised the actual conduct of the studies; wrote the reports and presented the final reports to clients, and in some cases prepared reports for publication.

Q About how many projects did you work on during the time that you were at Tabershaw/Cooper?

A Approximately seven or eight.

Q Could you tell me what those projects were, please?

A There were studies of mortality of persons employed in several different industries. These included lead smelters and battery plants. That was one project -- petroleum refinery workers, aluminum workers, lead chromate workers, populations of general chemical workers.

There may have been more, but I cannot recall at the moment.

Q Did you design those studies?

A I designed all except the study of lead smelter and battery workers.

Q Can you describe for me how you designed the mortality study involving petroleum workers?

MR. FEATHERSTONE: What is the relevance of that?

MS. STEIN: I am inquiring into Dr. Gaffey's experience.

MR. FEATHERSTONE: Dr. Gaffey did not do an epidemiological study of workers for the purposes of this case. Now, where are we going through all these studies in industries and of chemicals that have no bearing on this case, Ms. Stein?

MS. STEIN: Well, I don't agree that the studies that he has just described have no relevance to this case, especially inasmuch as some of them deal with organic chemicals and the specific studies which he just referred to refer to environmental exposure and I think I am certainly entitled to inquire into that.

MR. FEATHERSTONE: We will let you go a little bit further, but we are not going to sit here and go through each of the seven or eight studies, going through the design, who or what was studied, the results or what the conclusions were because they are in those specifics basically irrelevant to this lawsuit.

You can answer the pending question.

MS. STEIN: Are you --

MR. FEATHERSTONE: But I will at some point cut him off.

MS. STEIN: Fine, then I will be happy to go to the Judge.

MR. FEATHERSTONE: By all means.

Do you recall what the pending question was?

THE WITNESS: I will ask the reporter to read it back, please.

(Question read.)

BY THE WITNESS:

A We began by getting an inventory of all petroleum refineries in the United States. This was obtained from a publication called the Oil and Gas Journal which publishes a biannual census.

Given this inventory, we divided the plants up by region, the intention being to select a sample of plants that were reasonably representative of all petroleum plants by region.

We also divided after that and in addition to that, we divided the plants up by their size so that we could determine whether we were getting a representative sample of plants by size.

Within each of these regions and size classifications, we selected initially a small number of plants, two or three, I believe, in order first to determine whether the plants generally kept past records and in sufficient detail for us to carry out the investigation and also to determine what the resources and costs would be to visit those plants and collect data.

Having done this, we prepared estimates for subsequent statistical collection and within each of these geographic groups, we selected plants, a total of seven, I believe.

In the process of selection, we deliberately underrepresented the smaller refineries because we were aware that those were being phased out and that conclusions, if they were to be applicable to the future, would probably, should be confined to medium and large size refineries.

We went to each refinery and identified every individual who had worked for at least one year, any time of the decade between 1952 and 1961 -- I beg your pardon -- 1962 and 1971.

We photocopied the records of these people and from the plant obtained knowledge of whatever of those people, whoever of those people's vital statistics was known to the plant. For certain number of these people, the plant was therefore able to tell us whether they were definitely alive or definitely dead, and if they were said to be dead by the plant, we verified this by checking at the plant the death certificate. If the plant did not have a death certificate, we did not consider them dead but held them in abeyance for further investigation.

After this we took the people whose vital statistics was not confirmed by this earlier process and who had left the employment. In other words, we

had studied everybody who ever worked in that plant in that decade, whether or not they were still in the plant.

Through the use of the Social Security Administration and other resources, we were able to follow these people and determine whether they were alive or dead. Ultimately out of the 20,000 people in the study, we succeeded in following approximately 99 percent of them.

Given the information on whether these people were alive or dead and for the deaths, the information on cause of death from the death certificate, we then calculated (1) the number of deaths that we observed from each cause, and (2) the number of deaths that we would have expected from each cause if the people in our study at every age and at every year had behaved like the U.S. male population.

BY MS. STEIN:

Q These were all male workers?

A Yes, correct.

(Mr. Richard J. Phelan left the deposition room.)

MR. FEATHERSTONE: Stick around, it only gets better, Dick.

BY THE WITNESS:

A We then summarized the results of the study by presenting the ratio of observed to expected deaths for each of the large number of causes. We did this further for different subgroups in the population that had been hired at different dates.

The report of this was then provided to the client and made generally available.

BY MS. STEIN:

Q Who is the client?

A The American Petroleum Institute.

Q What were the conclusions, Dr. Gaffey?

A The conclusions were that there was no cause of death for which there were statistically significant excesses from any cause of death; however, for one group of causes, lymph cancers, there were excesses that appeared to warrant further investigation.

Q In what year did you finish the petroleum refiners' study?

A I believe it was in 1974.

Q Was that ever published?

A No, it was made available to the client and to the Federal Government, but it was never published because the client wanted to update the study further.

Q Were you involved in that update?

A No. The update is now being done by our private consulting organization.

Q When you say made available to the Federal Government, was it presented in the context of some sort of rule-making or standard-setting procedure?

A Not to the best of my recollection. A copy of the final report was sent to NIOSH and I believe to OSHA.

Q I believe you also said you were involved in the design of mortality studies for general chemical workers, is that correct, during the time you were at Tabershaw/Cooper Associates?

A We were involved in one particular study of one particular plant.

Q What did that study involve?

MR. FEATHERSTONE: You are not going to answer that question in that way.

Do you want to know what chemical and what plant, Ms. Stein?

BY MS. STEIN:

Q What chemical and what plant?

A I can't answer the question about chemicals because it was a general chemical plant in which large

numbers of chemicals had been used over a period of time.

Q Were you examining for exposure to one particular chemical?

A No. We were trying to characterize the overall mortality in the plant.

Q What were the factors that you looked at in designing that study?

A They were almost identical to what was involved in the study of petroleum refinery workers except in this case we had only one plant to look at.

Q In either of these studies you have just discussed, did you account for any confounding variables?

A We accounted for the variables of age, race and sex.

Q In both?

A In both of the studies.

Q Were there any confounding variables that you looked at in one study that you did not look at in another?

MR. FEATHERSTONE: May I hear the question, Thea?

(Question read.)

MR. FEATHERSTONE: I object to the form of the question.

Are we still speaking of two studies that he has so far identified?

MS. STEIN: That's right.

MR. FEATHERSTONE: That is not what your question impugned. You said another study, leaving it vague.

The question, Dr. Gaffey, refers to the oil refinery study and this chemical plant study that you have identified. Do you understand that?

THE WITNESS: I do.

BY THE WITNESS:

A The answer is no, there were no confounding factors unique to one of the studies.

BY MS. STEIN:

Q In other words, you did not look at smoking or alcohol consumption?

A No, we did not.

Q What were your conclusions on this study of a single chemical plant with regard to causes of death?

A To the best of my recollection, our major conclusion was that the number of deaths were so small that it was not possible to make any conclusions, given the age of the plant and the small size of the plant population.

Q With respect to the two studies that you have

just talked about, did you look for the specific chemicals to which the workers were being exposed?

A No, we did not.

Q After the time that you served as Director of Health and Epidemiological Studies at Tabershaw/Cooper Associates, you became the Senior Epidemiologist at Stanford Research Institute, is that correct?

A That is correct.

Q What did you do there?

A Very much the same thing that I had done at Tabershaw/Cooper. That is, I prepared proposals of design studies, supervision of data collection and analysis, the writing and presentation of reports.

Q Let me back up for a minute.

During the time you were at Tabershaw/Cooper, were you involved in any studies that were submitted that were done under contract of the Federal Government?

A Yes.

Q What study or studies were those?

A I participated in a report contracted for by the then Federal Energy Administration to review EPA studies of respiratory morbidity.

Q How did you conduct that review?

MR. FEATHERSTONE: Describe that very generally, Doctor.

BY THE WITNESS:

A We compared the conclusions.

BY MS. STEIN:

Q Excuse me. Did you understand my question?

A Yes.

MR. FEATHERSTONE: Did you understand my instruction?

THE WITNESS: Yes.

MR. FEATHERSTONE: Fine.

BY THE WITNESS:

A We compared the conclusions that EPA drew from their series of studies with the data on which they based the conclusions and evaluated any discrepancies that appeared to us to exist.

BY MS. STEIN:

Q What were the criteria you used in comparing the EPA data, EPA conclusions with the data and evaluating any discrepancies that appeared to exist?

A Much of the EPA data showed the relationship between various reported symptoms and various reported measures of air pollution. We used standard statistical techniques to fit curves to the data and compared those with the curves that the EPA had developed from the same

data.

Q Was there a particular substance that was involved in this work?

A Not to the best of my knowledge. There was a particular exposure context.

Q What was that?

A They were looking at exposure to air pollution in various urban areas.

Q What was the conclusion of your work regarding the EPA conclusions and vis-a-vis the data?

A That the EPA conclusions were certainly not based on standard techniques for fitting curves.

MR. FEATHERSTONE: It seems to be a problem that transcends a lot in EPA.

BY MS. STEIN:

Q What are the standard techniques that are used for fitting data to curves?

A The methodology is called the Least Squares.

Q L-e-a-s --

A L-e-a-s-t Squares.

Q What does that method involve?

A It involves fitting a curve that minimizes the squared differences between the points on the curve and the observed points to which the curve is to be

fitted.

Q Can you explain that in layman's terms?

MR. FEATHERSTONE: I object to the relevancy. Go ahead, Doctor.

BY THE WITNESS:

A To the best of my ability, no curve ever fits data perfectly, so for each observed point that one has, there is usually a difference between the position of that point and the position of the curve which is drawn through a center point.

When one tries to fit a curve, one wants to minimize this discrepancy between the observed points and fitted points as nearly as possible. And it turns out for theoretical reasons that the best measure of this overall discrepancy is to take the difference between the observed values and the values predicted from the curve, to square those differences and add them up and then, let us say you take the curve that misses the square of these of necessity. There are techniques for doing that directly without going through the kind of graphical procedure in that area, but these procedures are equivalent to just what I have just described.

BY MS. STEIN:

Q Is there a name for these procedures?

A It is called Least Squares.

Q The other.

A Oh, yes. One uses calculus and in particular calculates the derivative of the curve with respect to the technical parameters, creates equations which are then solved to give the parameters of the curve in terms of the original data.

Q Are there any other standard techniques that are used?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A The other technique is almost universally used, is called the maximum likelihood technique.

BY MS. STEIN:

Q What is that?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A The maximum likelihood technique in ordinary language says that we should pick the curve that makes it most likely that we would have seen what we actually saw in terms of the observed data.

BY MS. STEIN:

Q Are these general statistical techniques or are they related to biostatistical work?

A They are general statistical techniques.

Q And they are applicable to biostatistical work?

A Yes.

Q Dr. Gaffey, what is your training in epidemiology?

A A large part of the practice of occupational epidemiology is the application and use of statistical techniques.

I have training in statistics. I have read extensively in epidemiological text; I have as part of my employment experience with the California School of Public Health and with the California Health Department, worked with medical epidemiologists and I have myself practiced as an occupational epidemiologist for a good ten years.

Q Are there specific courses that epidemiologists take?

MR. FEATHERSTONE: Today?

MS. STEIN: Today.

MR. FEATHERSTONE: Objection, relevancy.

MS. STEIN: He is practicing today.

MR. FEATHERSTONE: He is not going to school today.

BY MS. STEIN:

Q You may answer, Doctor.

A Yes, there are.

Q What are those?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A They will vary from one institution to another, but they have a title such as Basic Epidemiology; The Epidemiology of Infectious Diseases; Chronic Diseases of Epidemiology; Epidemiology of Cancer; Occupational Epidemiology and so on.

BY MS. STEIN:

Q What were the components of those courses other than statistical components?

MR. FEATHERSTONE: Objection, relevancy; also I object to the lack of foundation.

MS. STEIN: Whether he is teaching courses --

MR. FEATHERSTONE: You have not established that he is in fact teaching courses. I am not sure that he in fact can answer that question, Ms. Stein.

BY THE WITNESS:

A I can only speculate on what they put in some courses when I was teaching them.

MR. FEATHERSTONE: Do not speculate. She is not entitled to that.

BY MS. STEIN:

Q What did you teach when you were lecturing on epidemiology at the U.C. Medical School in San Francisco from 1964 to 1979?

A I taught basic statistics to first year medical students.

Q Is there anything else that you taught during that time?

A No.

Q What did you teach while you were a lecturer in biostatistics in the U.C. School of Public Health from 1961 to 1979?

A I taught occasional graduate courses in biostatistics to graduate students in biostatistics.

Q Is a biostatistician andepidemiologist the same thing?

A Their talents overlap and many practicing epidemiologists have in fact formal training in biostatistics.

Q What are the differences between a biostatistician and an epidemiologist?

A An epidemiologist in general terms will have more background in medicine than a biostatistician.

Q Do you have any background in medicine?

A As part of my training in psychology, I have

had courses in physiology, anatomy and zoology.

Q Anything else in terms of background in medicine?

MR. FEATHERSTONE: You mean formal education?

MS. STEIN: That's right.

BY THE WITNESS:

A No.

BY MS. STEIN:

Q Do you have any background in ecology, Dr. Gaffey?

A No, I do not.

Q With respect to your membership in associations and societies, are there any certification requirements to become a member of the American Association for the Advancement of Science?

A No, there are not.

Q Are there any certification requirements to become a Fellow in the American Public Health Association?

A Fellows are elected. Names are proposed and they are elected by vote of the group of Fellows then in existence.

Q Do you know what the criteria are for election?

A No, I do not.

Q Are there any certification requirements for

the American Statistical Association?

A No.

Q Are there any certification requirements for the Biometric Society?

A No.

Q Are there any certification requirements for the Institute of Mathematical Statistics?

A No.

Q Are there any certification requirements for the New York Academy of Sciences?

A No, there are not.

Q Are there any certification requirements for the Royal Society of Health?

A Yes, in the sense that the applicant is required to present a review of his applications, of education and employment history.

Q This is as part of the application for membership?

A That is correct.

Q Are there any certification requirements for the Society for Epidemiologic Research?

A No.

Q With regard to the list of your publications, I would like you to go through that and if there are

any of that list that have not been subject to peer review, I would like you to give me the title of that publication or publications.

A On the second page of the list of publications, the last publication on the page is not a peer reviewed paper. The title is "A Brief Overview of Occupational Epidemiology."

Q Are there any others?

A No.

MR. FEATHERSTONE: Ms. Stein, are these check marks on Exhibit 1 yours?

MS. STEIN: Let me see this.

Yes. Let me give you a copy of this. We will re-mark one that does not have any marks on it.

MR. FEATHERSTONE: Do you want him to do anything with Exhibit 2?

MS. STEIN: Yes, I would like to have Dr. Gaffey read it.

(Gaffey-USA Deposition Exhibit No. 2 marked for identification, 6/3/82, TLU.)

BY THE WITNESS:

A That is a copy of the review of epidemiology literature on PCBs which I believe I prepared and which

was submitted to the EPA late last year.

BY MS. STEIN:

Q Was Exhibit 2 peer reviewed, Dr. Gaffey?

A Not as of this date.

Q Do you have intention to have it peer reviewed?

A It is scheduled for publication as part of proceedings of a Michigan symposium on PCBs. All papers in those proceedings are to be peer reviewed.

Q Is that the symposium that was held in Lansing, Michigan in mid-March?

A That is correct.

(Gaffey-USA Deposition Exhibit No. 3 marked for identification, 6/3/82, TLU.)

BY MS. STEIN:

Q Dr. Gaffey, I am going to show you a three-page list of publications and ask you if that reflects the documents that you referred to in preparation for this deposition.

A Yes, yes. I believe that is, yes.

Q Are there any documents that you looked at in preparation for this deposition and which do not appear on Exhibit No. 3?

A Yes.

Q What are those, please?

A I reviewed the depositions of Dr. Kimbrough and Dr. Humphrey. I reviewed data from the State of Illinois on PCB levels of fish caught in Illinois waters of Lake Michigan.

I have reviewed data on fish caught in Waukegan Harbor and immediately outside the Harbor and I have reviewed a report by Dr. Thomann on Mathematical Modeling of the Distribution of PCBs.

Q Anything else?

A That is all, to the best of my recollection.

MR. FEATHERSTONE: Did you review the Illinois Creel Survey?

THE WITNESS: I beg your pardon.

BY THE WITNESS:

A (Continuing.) I also saw a survey done by the State of Illinois of the Distribution of Fish Found in a Typical Fish Catch.

BY MS. STEIN:

Q How long did you spend in preparing for this deposition?

A If one includes the time spent in the review of epidemiology which is the main content of my background, I would say a total of perhaps a couple of months,

total time.

Q Does that include the time spent in preparation of the paper that has been marked as Exhibit No. 2?

A Yes, it does.

MR. FEATHERSTONE: In other words, you have given Ms. Stein an estimate of the time you have spent relating to this PCB issue generally, is that correct?

THE WITNESS: In effect that is so because my concern with those issues has been the review of those literature almost entirely.

BY MS. STEIN:

Q Have you read any animal toxicity studies in preparation for this deposition?

A No, I have not.

Q Have you read the deposition of Dr. Ringer?

A No, I have not.

MR. FEATHERSTONE: That was the last deposition.

MS. STEIN: Just in case.

BY MS. STEIN:

Q Dr. Gaffey, could you define for me a mortality study?

A A mortality study is the study of the death rates and causes of death in a population related to various characteristics of that population.

Q Let me go back.

Other than the mortality studies that you mentioned in connection with your work at the Tabershaw/Cooper Associates firm, have you ever developed any other mortality studies?

A Yes.

Q What were those?

A When I was employed at Stanford Research Institute.

MR. FEATHERSTONE: Wait. Do you want the position he held when he developed the mortality study or do you want the specific mortality studies?

MS. STEIN: No, the specific mortality studies.

MR. FEATHERSTONE: Go ahead, Doctor.

BY THE WITNESS:

A One mortality study of gold miners, one of pump and paper workers, one of people employed in the manufacture of paints and varnishes; one study of the entire work force of a major petroleum chemical company. That's all.

BY MS. STEIN:

Q Did you design these studies?

A Yes.

MR. FEATHERSTONE: If you reach a convenient place,

Ms. Stein, maybe we could break for a few minutes.

MS. STEIN: Why don't we do it right now.

(Brief recess had.)

BY MS. STEIN:

Q Dr. Gaffey, let me back up a minute.

With regard to the mortality studies that you were involved in at the time that you were at Tabershaw/Cooper Associates, Inc., and those that you designed, were the criteria factors that you took into account in designing those studies similar to the program that you followed with regard to the petroleum workers?

A Yes, except in the cases -- I must break this up a little.

They were similar except that in the case of the study of aluminum workers, the records in the plants were such that we had to be satisfied we were taking all the plants that had adequate records rather than making a random selection of plants.

Q Dr. Gaffey, with regard to the limitations regarding adequate records in the aluminum plants, did you feel that that in any way influenced the results of that study?

A No, because the plants that lacked adequate

records are not different in any systematic way, either in the process that was used or in their range in the plants for which there were adequate records.

Q Were any of those studies that were done, any of those other studies, worked on during the time that you were at Tabershaw/Cooper, published?

A Yes.

Q Which one or ones were published?

A I did a study which I omitted to mention of vinyl chloride workers at Tabershaw/Cooper. That was published.

Also the study of lead smelter and battery workers that I referred to first, several analyses of that study were published in different publications. They are included in my CV.

Q Before the break you had mentioned four other mortality studies that you worked on, one on gold miners, one for pulp and paper workers, one for manufacturers of paints and varnishes and one for the workers of a major petroleum chemical company.

Were those done all at the time you worked at the Stanford Research Institute?

A Yes, although the last of those was at its beginning stages at the time that I left.

Q And did that study assess the risks of environmental exposure to a particular agent or agents?

A They assessed risk of an occupational exposure to particular agents and groups of agents.

Q What agent or agents were you looking at with respect to the gold miners?

A The ore in which this particular gold was contained also contained a form of asbestos. It was a form which was uncommon and for which there were no other recorded instances of exposure going back for several decades.

Q What was the conclusion that you reached in your study?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A The study concluded that there were no excess deaths from asbestos-related causes in that population of gold miners.

BY MS. STEIN:

Q What were the confounding variables that were taken into account in that study?

A Smoking and ethnic origin in the sense that a substantial portion of the miners were American Indians and a count had to be taken of this to decide whether

there was excess mortality.

Q Is that because as compared to the general population, they have a different mortality rate?

A There appears to be reason to believe that they have a different mortality rate, but statistics for them are so unreliable that they were taken aside and analyzed separately.

Q Do you recall, were smoking and ethnic origin the only confounding variables taken into account in that study?

MR. FEATHERSTONE: Again, objection to relevancy.

Go ahead and answer.

BY THE WITNESS:

A Of course, age and date of birth as was the case in those mortality studies generally.

BY MS. STEIN:

Q What was the agent or what were the agents that you looked at in the pulp and paper workers' study?

A The pulp and paper workers have a multiplicity of exposures, but they included chlorine, various sulfates, formaldehyde and a range of solvents used in various parts of the process.

Q Were any of those solvents chlorinated aromatic hydrocarbons?

A I don't recall because this study, again, was approaching its completion and not yet ready for analysis at the time I left Stanford Research Institute.

Q At the time that you left, had any conclusions been drawn in that study?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A Not to the best of my knowledge.

BY MS. STEIN:

Q What were the confounding variables that were taken into account in that study?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A Again, age, date of birth, race and sex.

BY MS. STEIN:

Q What were the agents or what was the agent looked at in the study involving the manufacture of paints and varnishes?

A Again, there were a range of exposures including those of solvents, various organic pigments, inorganic pigments. That is all I recall.

Q Were any of those compounds chlorinated?

A I believe that benzene was such a compound.

Q What were the conclusions that were drawn in

that study?

MR. FEATHERSTONE: Objection, relevancy.

BY THE WITNESS:

A As I recall there were excesses of certain cancers. I believe they were lymphatic cancers and leukemia. They showed no definite relationship to exposure and subsequent studies were begun to investigate that more carefully.

BY MS. STEIN:

Q Were you involved in the subsequent studies?

A No.

Q With regard to the mortality study involving workers of a major petroleum chemical company, was this study involving a nationwide work force or one plant?

A It was a study of several plants over a region.

Q What was the name of the company?

A The name of the company was Texaco.

Q Were there particular agents that you were looking at in that study?

A The people in the study were classified, not by agents, but by the kinds of jobs that they had. I believe that later it may have been planned to identify agents that might have been associated with those particular jobs, but this study had reached only the preliminary data

collection stage at the time I left.

Q Can you define for me a morbidity study, what a morbidity study is, please?

A A morbidity study is a study of the risk of ill health as opposed to death in populations related to characteristics of those populations.

Q Is there some separate definition of ill health in the context of morbidity studies?

A No, there is a range of commonly used definitions.

Q Could you give me that range of definitions?

A They are very much the same as the ones I gave earlier: Medical absences, physician-diagnosed illness, disability, self-reported illness and symptoms.

Q Have you been involved in the design of any morbidity studies?

A Yes.

Q Can you tell me what those studies were?

A While I was at Tabershaw/Cooper I conducted a morbidity study whose purpose was not to measure morbidity but to determine whether it was feasible to conduct such a study.

Q What was your conclusion?

A Our conclusion was that the data on medical

absences were so variable that they were a better measure of effectiveness of management than they were of occupational hazards.

MR. FEATHERSTONE: This was in connection, I take it, of a particular client?

THE WITNESS: That is correct.

BY MS. STEIN:

Q Any other?

A That's all.

Q Is it fair to state that as part of your work you engaged in risk assessment?

A Could you define risk assessment more precisely?

Q Assessing the risk to human health of environmental exposures and environmental exposures includes occupational exposures.

A Yes.

Q Can you tell me what the techniques or tools are that you use in risk assessment?

A I conduct mortality studies of exposed populations and identify significant excess risks, if they exist.

Q What if they are insignificant excess risks? To your knowledge, what do you do with those?

MR. FEATHERSTONE: What do you mean by that, do you

mean how does he evaluate those?

MS. STEIN: Yes.

MR. FEATHERSTONE: The question is how do you evaluate insignificant excess risk.

BY THE WITNESS:

A They get evaluated by looking at the patterns of risk. For example, it would be an unusual that a morbidity study did not show an excess mortality from something since the usual such study will look at three or four causes of death. If these insignificant excesses appear to be balanced by equally insignificant deficits, then the reasonable evaluation is we are looking here at what one might call the noise level that results from the random variation one expects to see in reobserved deaths.

BY MS. STEIN:

Q For clarification, by significant or insignificant, we are talking about statistically significant?

A Yes.

Q Are there any criteria to determine what is statistically significant and what is not statistically significant?

A Yes, there are conventional techniques which are approximate but are generally used.

Q What are those techniques?

A The usual assumption is to assume that the observed deaths that occur have a poisson distribution.

MR. FEATHERSTONE: As in fish?

THE WITNESS: One man's meat is another man's poisson.

MR. FEATHERSTONE: Do you remember where you were in your answer?

THE WITNESS: Yes.

BY THE WITNESS:

A Assuming this probability distribution, it is then possible to identify limits beyond which it would be relatively improbable to see numbers occurring by chance alone. The level of probability generally used is 5 percent.

BY MS. STEIN:

Q A poisson distribution is probability distribution, is that right?

A Yes, it is. When the numbers of expected deaths are large, say, five or more, it is usual to use not the poisson distribution but an approximation to it called the normal distribution.

Q What is the normal distribution?

MR. FEATHERSTONE: Were you asking for a definition,

Ms. Stein?

MS. STEIN: Yes.

MR. FEATHERSTONE: She wants a definition of the normal distribution.

BY THE WITNESS:

A In nontechnical terms, if we observe a value whose numerical value is the result of a large number of independent interacting factors, this value has a probability distribution which is common to many different fields: Epidemiology, biology, astronomy.

This distribution has a specific formula that is known as the normal distribution. Statisticians who deal with samples above five tend to always use a normal distribution or some variation of it as an adequate approximation to the true distribution that they actually have.

BY MS. STEIN:

Q Are these interacting variables defined somewhere?

A In the case of the poisson distribution, they are not because it is possible mathematically to prove that for large numbers of expected deaths, the poisson distribution is classically approximated by the normal distribution.

Q What are these variables?

A I beg your pardon?

Q Are these variables in terms of numbers you are talking about?

A Yes, I am talking about observed numbers such as observed numbers of deaths.

Q Do you use any mathematical models in your risk assessment work?

A No, I do not.

MR. FEATHERSTONE: Would you read the question back, Thea?

(Question read.)

MR. FEATHERSTONE: In this question, Ms. Stein, were you leaving out the use of the statistical techniques that he has described?

MS. STEIN: Right.

BY MS. STEIN:

Q Dr. Gaffey, could you give me your definition of a negative study in an epidemiological sense?

A A negative study, I assume here we are talking about a negative study of a population that has a certain exposure?

Q That is right.

A A study is negative if the risk of ill health

calculated in the exposed population is either no greater than expected or shows no relationship to the amount of exposure or the interval since exposure began or cannot be repeated in independent studies.

I assume here that we are talking about a study for which there are no confounding variables.

MS. STEIN: Could you read back the first sentence of the answer?

(Record read as requested.)

BY MS. STEIN:

Q When you say you assume we are talking about a study where there are no confounding variables, would that include in your mind a study where confounding variables had in fact been taken into account and controlled for --

A I would say such a study did not have confounding variables, for all practical purposes.

Q What is your definition of a no-effect study?

A No-effect study --

MR. FEATHERSTONE: Is that a term you are familiar with, Dr. Gaffey, a no-effect study?

THE WITNESS: I have heard that term used in connection with animal studies, but never in connection with human epidemiology.

BY MS. STEIN:

Q What is your definition of a positive study?

A I would just turn around the definition that I gave of the negative study. That is, a positive study is one in which the risk of ill health in the exposed population is greater than expected and the effect is greater with increasing duration of exposure or increasing interval from the beginning of exposure and is beyond what would be expected by chance, that it is statistically significant and can be confirmed in repeated independent studies.

Q Is there a name to your studies which show an excess of a risk to ill health that is not statistically significant?

MR. FEATHERSTONE: Are you assuming there are no other risks of the same type of exposure?

MS. STEIN: Wait a minute. I don't know what you are asking, Bruce.

MR. FEATHERSTONE: I don't think that you can ask the Doctor to base that on one fact unless you tell him that you are assuming there are no other tests that show the same thing; for instance, no other independent test, one test standing alone as this one test standing alone that shows a slight but significant or not statistically

significant excess. Is that your assumption?

MS. STEIN: I see where the confusion is. I was talking about studies and you are talking about a test.

THE WITNESS: I understood I was asked if there was a name for studies of that kind.

BY MS. STEIN:

Q That is the question.

A I am not aware. I am aware, however, of a categorical name like positive or negative.

Q Have you ever encountered studies where there is an excess but it is not a statistically significant excess for a particular parameter that is being looked for?

MS. OLIVER: Just a minute. The clarification Bruce was trying to make, you were talking about one study that shows that, or are you talking about several studies that show an excess in significant risk? Is that it?

MR. FEATHERSTONE: Let's go off the record.

(Discussion off the record.)

BY MS. STEIN:

Q Have you ever encountered a study where there was an observed excess of a particular health effect that was not statistically significant?

A Yes.

MS. STEIN: Off the record.

(Discussion off the record.)

BY MS. STEIN:

Q Dr. Gaffey, could you define the term dose response relationship?

A A dose response relationship is the relationship between the risk of ill health and the amount of exposure to a particular agent or environmental factor.

MR. FEATHERSTONE: Doctor, you are referring to how it is used in the context of epidemiological study?

THE WITNESS: My thinking of this is in how it is used in a human epidemiological study with exposure to be measured either by level of the exposure or duration of exposure to the substance or agent in question.

BY MS. STEIN:

Q Would you describe for me linear relationship?

A Two variables of a linear relationship in plain language, when plotted on a graph, they produce a group of points that look as if they are in a straight line.

Q Could you define for me, Dr. Gaffey, the phrase "route of exposure." We are talking in epidemiologic context.

A Route of exposure would be the particular manner

in which the substance to which somebody is exposed enters in or touches on his body.

Q Based on your experience and education, are you aware of any agents with respect to which the route of exposure affects the kind of effects produced?

MR. FEATHERSTONE: Would you read that question?

(Question read.)

MR. FEATHERSTONE: By kind of effects, you are not talking about the size of the response? You are talking about whether a particular response happens?

MS. STEIN: That is correct.

MR. FEATHERSTONE: Is that correct?

BY THE WITNESS:

A Yes, I am.

BY MS. STEIN:

Q Could you give me some example, please?

A I can give two. One is tobacco in which the consequence of cigarette smoking and chewing prove to be quite different in terms of sources of area in which cancer appears.

The other is PCBs in which it appears that whether or not dermatitis occurs is a function of whether or not there is skin exposure as opposed to inhalation or ingestion.

Q What is the basis for your response with respect to PCBs?

A The cross sectional studies of occupationally exposed persons that I looked at in my review shows a pattern of dematitis and chloracne that is consistent with this explanation and has been offered as an explanation by several of the authors of those studies.

Q What is a cross sectional study?

A A cross sectional study is one in which one examines a population at a given moment of time and looks at a relationship between the appearance of various measures of ill health and history of exposure of that population.

Q With respect to the pattern that has been offered as an explanation, could you point out in the bibliography of your paper which has been marked as Exhibit 3, which studies you are referring to?

MR. FEATHERSTONE: Can I have the question?

(Question read.)

MR. FEATHERSTONE: I object to the question insofar as it suggests that a pattern has been offered as an explanation. My understanding of the witness' testimony was the pattern is consistent with this, which was his explanation a couple of answers ago, that the pattern has

been offered as an explanation by several authors.

MS. STEIN: I thought that is what I asked.

MR. FEATHERSTONE: You want to know the authors that have made observation and offered explanation?

MS. STEIN: Yes.

MR. FEATHERSTONE: That's fine.

BY THE WITNESS:

A Hara, et al.; Kitamura, et al.; Chase, et al. There may be more, but these are the ones I can recall.

BY MS. STEIN:

Q Dr. Gaffey, could you give me your explanation of biomagnification, please?

A This would be a layman's definition.

I think it is the process by which substances in the environment may be concentrated in certain species of plants or animals in that environment.

Q Let me ask for clarification: May be concentrated in species or concentrated in individuals of a species?

A I am sorry, in individuals of a species, plant or animal.

Q Let us go back for a minute to the route of exposure. I had asked you whether or not the route of exposure could affect the kinds of effects produced.

Let me ask whether you are aware of any

studies which purport to show that the route of exposure affects the degree of effects produced?

MR. FEATHERSTONE: Are we still on PCBs or are we to --

MS. STEIN: To anything at this point.

BY THE WITNESS:

A I cannot at the time name any such studies.

MR. FEATHERSTONE: I think the question was are you aware of any.

BY THE WITNESS:

A (Continuing.) No, I am not.

BY MS. STEIN:

Q Dr. Gaffey, would you give me your understanding of the subject matter to which you are going to testify at trial?

A It is my understanding that I will testify as to the epidemiology studies that have been done on PCBs and my opinion of what they tell us about the health effects of PCB.

Q Then your testimony will be limited to human health effects based on these particular epidemiological studies that you have reviewed?

A Human health effects based on these particular epidemiology studies and on the other material that I

stated I had reviewed.

Q Do you have an opinion as to whether American commercial PCB mixtures as sold presently are a risk to human health?

A I do have an opinion.

Q What is your opinion?

A That --

MR. FEATHERSTONE: Wait a minute. I object to the question as indefinite and vague. Are you assuming particular exposure in a particular environment?

MS. STEIN: No.

MR. FEATHERSTONE: Are you assuming any exposure whatsoever? How can you answer a question about a potential risk unless you tell the person responding there is a potential exposure, and if there is a potential exposure, what that potential exposure may be. It is entirely possible the commercial mixtures of PCBs as sold do not have any exposure to humans in certain circumstances and then again it is entirely possible there may be an exposure.

BY MS. STEIN:

Q Do you understand the question, Dr. Gaffey?

A Could you repeat it, please?

(Question read.)

BY THE WITNESS:

A At present with the levels that occur in the occupational employed populations and in the environment, there is no evidence that PCBs are related to any untoward health effects.

BY MS. STEIN:

Q Could you tell me what you mean by any untoward health effects?

A I mean illnesses, diseases, symptoms, excesses of causes of death.

Q And are you including in your answer regarding health effects, terretogenicity?

A Yes.

Q Are you including mutagenicity?

A Yes.

Q Are you including fetotoxicity?

A Yes.

Q Are you including effects on reproduction generally?

A Yes.

Q Are you including behavioral manifestations?

MR. FEATHERSTONE: For instance?

BY MS. STEIN:

Q Retardation.

A Retardation, yes.

Q Anything such as hyperactivity?

MR. FEATHERSTONE: Do you mean is that included?

BY MS. STEIN:

Q Is that included?

A No, that is not included.

MR. FEATHERSTONE: Ms. Stein, just so I am clear when you say you are including, whether something is included or not, by included you mean included or not included in his original opinion that there is "no evidence of any untoward health effects"?

MS. STEIN: That is correct.

BY MS. STEIN:

Q Would you define chloracne as an untoward health effect?

A Yes, I would.

Q I am going to refer you now to what has been marked as Deposition Exhibit No. 3, Dr. Gaffey. Do you recall whether the bibliography that has been marked as Exhibit No. 3 is the same bibliography that you appended to your paper?

A With one exception of the bibliography here which has one additional paper that was published in 1982 which I added and subsequently revised this to

include the mention of that paper.

Q Which one is that?

A That is Chase, et al. It is that one.

MR. FEATHERSTONE: On the first page, three or four from the bottom, Liz.

BY MS. STEIN:

Q Are these references listed on Exhibit 3 the extent of the literature that you reviewed in formulating your opinion with regard to the potential risk to human health of American commercial mixtures of PCBs?

MR. FEATHERSTONE: Before you answer that, I again object because you have not specified the exposure and he has already identified other documents that were shown to him.

MS. STEIN: Well, if he knows.

MR. FEATHERSTONE: But you have already asked that question. You asked him earlier on in this deposition whether these documents listed on Exhibit 3 are all the documents and he said no, and then he went and ticked off a list of things he looked at.

MS. STEIN: I think we are talking about two different things, Bruce: Ones that he may have looked at in preparation for the deposition as opposed to whether or not something forms the basis for his opinion.

THE WITNESS: As far as the basis for my opinion about the health effects of PCBs, in general these represent the documents on which I depended.

MR. FEATHERSTONE: You are pointing to Exhibit 3 of your deposition?

THE WITNESS: I am pointing to Exhibit 3 which includes among other things, some studies of Japanese PCB compounds.

MS. STEIN: We can take a break now if you want, for lunch.

(At 12:45 o'clock p.m., a lunch recess was taken to 1:30 o'clock p.m. this same day.)

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 78 C 1004
	)	
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
	)	
	)	
Defendants.	)	

June 3, 1982,

1:30 o'clock p.m.

The deposition of WILLIAM R. GAFFEY resumed pursuant to noon recess at Suite 6000, 200 East Randolph Drive, Chicago, Illinois 60601, before Thea L. Urban.

PRESENT:

MS. ELIZABETH STEIN,

MS. ROSEANN OLIVER,

MR. BRUCE A. FEATHERSTONE.

ALSO PRESENT:

MR. MARK FERGUSON.

- - -

WILLIAM R. GAFFEY,

called as a witness herein, having been previously duly sworn, was examined and testified further as follows:

DIRECT EXAMINATION (Resumed)

MR. FEATHERSTONE: You were answering your question about the health effect of PCB.

THE WITNESS: Before we begin, I answered with environmental effects and I think I said it was environmental and occupational which was a slip, because in the case of heavily occupational groups there is a health effect which is dermatitis and chloracne. But I think I referred to this earlier in talking about it in my paper, but that was a slip because of my concentration on environmental exposures rather than occupational.

BY MS. STEIN:

Q Let me make sure I understand.

With respect to chloracne, you think there is a risk in terms of occupational exposures but not with respect to environmental exposures?

A That is true both of the chloracne and other dermatitis, yes.

Q When you were talking about environmental exposures then, I guess for the rest of the questions we should be clear that if I say environmental exposure,

then you would not include occupational exposure within that term, is that correct?

A That would be my understanding, which I think is one of the problems I had. I oppose occupational exposure on the one hand and environmental exposure on the other.

Q When you talk about environmental exposure, did you have a particular level of exposure in mind?

A No, I am talking simply about the exposures of people in an ordinary environment which is not occupational.

Q Does your opinion with regard to exposure to American commercial mixtures of PCBs as sold in the occupational context assume that those mixtures contain no contaminants?

A You are talking now about the occupational exposures of people who are said to be exposed to PCBs?

Q That is correct.

A No, the studies that I have looked at have been studies of effects of exposure and no matter what the exposure, the conclusions about effects are still the same.

Q Do you know whether any of those studies that you have reviewed as a basis for your opinion ever mention,

and we are talking now about the occupational studies for a moment, do you know whether those occupational studies even looked for or considered the possibility of contaminants in the PCBs to which that population was being exposed?

A I don't know.

Q When you were interpreting those studies, did you assume that there were no contaminants present in the PCBs?

A No, I did not. What I did was look at the effects of the exposures and ask myself whether the effect of this exposure, occupational exposure, whether there are any effects. It turns out there were none, so no matter what the exposures were in terms of contaminants, if there were no occupational effects, that result is still valid no matter what the exposures are.

MR. FEATHERSTONE: And you are excepting here dermatitis and chloracne as you testified earlier? She is talking about specifically, as I understand it, the effect of occupational exposure studies.

MS. STEIN: Yes.

THE WITNESS: Yes, that is correct, and when I looked at the reports of chloracne and dermatitis, these studies did not consider whether there were contaminants

involved nor did I in my interpretation of them.

BY MS. STEIN:

Q With respect to those occupational studies that looked at things other than chloracne or dermatitis, do you know whether those, and we again are still talking about the occupational studies, do you know whether those studies took into account whether or not there were contaminants in the PCBs?

A They did not, to the best of my recollection.

MR. FEATHERSTONE: Well, wait a minute now.

These studies that you did were exposures to PCBs and if there were anything in the PCBs such as contaminants, and then, Ms. Stein, you say they would be in whatever was exposed to these workers. I think you have two different questions. One is whether anybody had a contaminant in the PCBs to which the workers were exposed, and the other question is if not, that tends to rule out the possibility that that was there.

I don't know. I think the studies are clear that commercial mixtures of PCBs were in these plants. Workers were exposed to them and there were or were not findings depending on the studies, and in fact that nobody looked for contaminant doesn't mean there might not have been contaminants.

MS. STEIN: I have been asking whether Dr. Gaffey knew if it was even looked for or whether the people conducting the study assumed them to be present or not, irrespective of -- do you see what I am saying, Bruce?

MR. FEATHERSTONE: If the question is, Dr. Gaffey, did the people who conducted these studies look for contaminants in the PCB mixtures to which the workers were exposed, that is a proper question. But I don't know from the answer to that, which I assume would be "no" or "not to my knowledge," because I am not aware of it, for instance, and I don't think you can go from that conclusion to a conclusion that if there had been dibenzofurans or whatever other contaminant in whatever mixtures to which these workers were exposed, I don't know you can say positively that would make any difference because they were exposed to whatever they were exposed to which you assume was there or wasn't. Do you follow me?

MS. STEIN: I didn't draw any conclusions. I was asking Dr. Gaffey for his knowledge.

MR. FEATHERSTONE: I think your questions are not that clear.

MS. STEIN: If they are not, Dr. Gaffey can ask me to restate it and I will do the best I can.

MS. OLIVER: What is the question?

MR. FEATHERSTONE: There isn't any that I know of. Is there a question?

MS. STEIN: No, there was some testifying from Bruce.

(Laughter.)

MS. STEIN: Did you get down the laughing, Thea?

MR. FEATHERSTONE: Did you get that down, Thea? Don't worry, Liz. She is getting it all down.

BY MS. STEIN:

Q Dr. Gaffey, do you have an opinion as to what environmental exposure we are talking about now and we are talking about exposure other than in occupational context to American commercial PCB mixtures.

MR. FEATHERSTONE: I would --

MS. STEIN: Strike that.

BY MS. STEIN:

Q Do you have an opinion as to whether exposure to environmental residues of American commercial PCB mixtures presents a risk to human health?

MR. FEATHERSTONE: I object to the question as vague and indefinite, same problem exists in this question as with the other questions. There is no definition for

the witness of the amount of exposure, length of exposure or anything like that.

MS. STEIN: Were you going to pose an objection?

MS. OLIVER: No, that covers it. Thank you.

BY THE WITNESS:

A My opinion, exposures, environmental exposures of the levels we are experiencing, for example, the study of Michigan Sports Fish Eaters poses no threat to human health.

BY MS. STEIN:

Q By no threat to human health, do you mean no risk of adverse health outcome?

A That is --

MR. FEATHERSTONE: I object to the form of the question. Go ahead.

BY THE WITNESS:

A No risk associated with PCBs.

BY MS. STEIN:

Q Does your opinion assume the environmental residues of American commercial PCB mixtures contain no contaminants?

A No, my response does not assume that.

Q What does your response assume then?

MR. FEATHERSTONE: About what?

MS. STEIN: Presence or absence of contaminants.

MR. FEATHERSTONE: You may answer the question, Doctor.

BY THE WITNESS:

A I have made no assumption about the presence or absence of contaminants because there have been no health effects associated with these exposures, so whatever is contained in the exposures has not resulted in the health effects in these populations.

BY MS. STEIN:

Q Let me define health effect in terms of environmental exposure.

When you say no health effect, are you saying no physical manifestations as opposed to some sort of systemic abnormality?

MR. FEATHERSTONE: Do you understand that?

THE WITNESS: Could you define what is meant by systemic abnormality?

BY MS. STEIN:

Q For example, blood levels in excess of the normal range that are found in the population, elevated levels in adipose tissue. Test results on liver function outside the normal range, vital capacity changes, along that line.

MR. FEATHERSTONE: Before you answer that question, let me hear Dr. Gaffey's clarification earlier to Ms. Stein in light of the question she just asked.

(Record read.)

MR. FEATHERSTONE: I object to the question insofar as it suggests that what Ms. Stein says is a systemic abnormality.

THE WITNESS: Shall I answer it?

MS. STEIN: Please.

MR. FEATHERSTONE: If you can.

BY THE WITNESS:

A There are several things mixed up in here. Two of the phenomena that you mentioned are not health effects. They are simply levels of PCB in the blood.

In other words, those are not measures of the outcome. They are measures of the exposure.

MR. FEATHERSTONE: You better identify those two.

BY THE WITNESS:

A (Continuing.) The levels, as I understood it, of PCB in the blood and in adipose tissue. These are measures of exposure.

The other phenomena that you mentioned are outcome measures. The first of these was raised levels of several enzymes that are produced in the liver

and these have not been found in environmentally exposed populations.

BY MS. STEIN:

Q How about changes in vital capacity?

A Changes in vital capacity has not been found in environmentally exposed populations.

Q Have these liver enzyme changes or vital capacity changes been found in occupationally exposed populations?

A The answer is both yes and no. To the first, yes. The raised levels of various liver enzymes have been identified in relatively heavily exposed occupationally exposed populations. In one such population, a study of the vital capacity concluded that vital capacity was adversely affected in this group.

However, that study compared the vital capacity in the work force which most of whom were current or ex-smokers with a standard for vital capacity and that was based on a population of non-smokers.

Q Which study was that?

A That was the study of Warshaw, et al.

Q Do you know of any other studies that looked at vital capacity?

A I found none, no.

Q Dr. Gaffey, are you aware of any contaminants in American commercial PCB mixtures as sold?

A No, I am not.

Q Are you aware of any literature on the subject of contaminants in American PCB mixtures?

A No, I am not.

Q Are you aware of any environmental residues of American commercial PCB mixtures that contain contaminants?

A No, I am not.

Q Do you know of any study on the subject of environmental residue of American PCBs containing contaminants?

A No, I do not.

Q Dr. Gaffey, are you familiar with the site that is the subject of this litigation?

A Yes, in the sense that I have seen material about that site.

Q Have you ever visited the site?

A No, I have not.

Q Is the material that you have seen regarding this site the data from the State of Illinois regarding PCB levels in fish from the Illinois waters of Lake Michigan, data on fish caught in the Waukegan Harbor and

immediately outside the Harbor; the Thomann report and the Creel Survey?

A That is correct.

Q Would you include depositions of Dr. Kimbrough and Dr. Humphrey as well in that category?

A Yes.

MR. FEATHERSTONE: He has also reviewed which he did not mention, and I can tell you what else he has reviewed if you want to know it, Ms. Stein.

MS. STEIN: Of course I do.

MR. FEATHERSTONE: He ha seen diagrams of Waukegan Harbor. Am I correct, Doctor?

THE WITNESS: Yes, of course.

MR. FEATHERSTONE: He has seen, I will probably get the name of it wrong, but it is the EPA document that kind of summarizes what is allegedly in Waukegan Harbor and the North Ditch.

THE WITNESS: Yes.

MR. FEATHERSTONE: And the proposed dredging remedy. I think it was about an 80-page document. He has seen that as well.

I am searching my brain.

Is there anything else?

THE WITNESS: I have seen that, but I don't believe

I had an opportunity to read it in its entirety.

MR. FEATHERSTONE: But you read portions of it?

THE WITNESS: Yes, yes.

MR. FEATHERSTONE: I don't think, for instance, that he read in detail the proposed dredging remedy for Waukegan Harbor.

If I think of anything else during the course of the deposition, I will alert you to it.

MS. STEIN: Thank you.

BY MS. STEIN:

Q Dr. Gaffey, do you have an opinion as to whether the PCBs --

MR. FEATHERSTONE: Wait a minute, before you go on. I remember another document. Do you want it now or later?

MS. STEIN: Now.

MR. FEATHERSTONE: He saw at least one and maybe more than one document that I call the Absence of Harm in the Public Drinking Water in Waukegan.

Is that correct?

THE WITNESS: Yes.

MR. FEATHERSTONE: Letter to Mayor Morris is the specific one I recall authored by some EPA official.

THE WITNESS: I apologize. That is true and I have forgotten it.

BY MS. STEIN:

Q Dr. Gaffey, do you have an opinion as to whether the PCB residues in the Waukegan area, specifically the North Ditch -- do you know what I refer to when I say the North Ditch?

A Yes.

Q Waukegan Harbor and elsewhere on the environs of the OMC facility, whether exposure to those PCBs present a risk to human health?

MS. OLIVER: I am going to object to the form of the question. There is no evidence of other places on OMC property beside the parking lot, I think.

MR. FEATHERSTONE: And I will object to the form insofar as it is vague as to what is meant by the environs of OMC property.

BY MS. STEIN:

Q The parking lot area, Dr. Gaffey.

MR. FEATHERSTONE: Okay. You can answer.

With that qualification, let me have the question back.

(Question read.)

MR. FEATHERSTONE: The question is do you have an opinion.

BY THE WITNESS:

A Can I ask for one further clarification?

Do you mean exposures to people at those sites? You mean from people walking around the area?

BY MS. STEIN:

Q Yes.

A I have no opinion on that.

Q Do you have an opinion with regard to exposure to fish taken from those areas or drinking water from the enumerated areas or means other than just walking by?

MR. FEATHERSTONE: You are talking about exposure to humans in that way?

MS. STEIN: Yes.

BY THE WITNESS:

A Yes, I do.

BY MS. STEIN:

Q What is your opinion?

A If we may start with drinking water, in my professional opinion, there is no danger of health effects from drinking water because analyses have shown that PCB levels in drinking water are below the limit of detectability, that is, below 50 parts per trillion.

With regard to exposure from eating fish, in my opinion there is no danger to health because in

fact sampling of fish from the areas around Waukegan Harbor where fishing is common have shown levels of PCB to be in the fish were lower than the levels consumed by the sports fishermen who were studied by Dr. Humphrey and in whom there were no health effects found.

Q Is there any other basis for your opinion?

A Yes. That --

MR. FEATHERSTONE: Wait a minute. I object to the form of the question insofar as it even suggests that you asked for a basis of opinion. You first asked for an opinion and that is the opinion.

MS. STEIN: That's right.

MR. FEATHERSTONE: And all of a sudden we went to do you have any other basis for the opinion and I don't know where the other came from.

MS. STEIN: I believe you testified that he reviewed certain data and that was a partial basis for hi opinion.

BY MS. STEIN:

Q Is that correct, Dr. Gaffey?

If it is not, please tell me and I will rephrase my question.

MR. FEATHERSTONE: Her question is the data that you have listed and referred to in connection with Waukegan

Harbor, does that form a basis for your opinion.

THE WITNESS: Yes, it does. My opinion is based on two things: The information on health effects obtained from Dr. Humphrey's studies of Michigan sports fish eaters and the information about the effective levels of PCBs in fish caught near Waukegan Harbor, which I obtained from the other sources of data that I think I mentioned.

BY MS. STEIN:

Q Is there any other basis for your opinion regarding the risk to human health or lack of risk from exposure to PCBs in Waukegan Harbor, the North Ditch and the parking lot?

MR. FEATHERSTONE: Ms. Stein, are you excluding the literature that he reviewed?

MS. STEIN: I am trying to get out whether or not that literature is included as a basis.

MR. FEATHERSTONE: Do you understand her question?

THE WITNESS: Yes.

BY THE WITNESS:

A Particularly one paper from that literature by Kreiss, et al. is a direct part of the basis because this is also a study of a community in which by virtue of PCB level in fish, there was a relatively high exposure

of PCBs.

And in that community, again, no health effects were detected except a relationship with hypertension which was not confirmed in a study of higher level, occupational level.

MR. FEATHERSTONE: Just to clarify, Ms. Stein wants to know if in formulating your opinion on Waukegan Harbor, you rely in your view in part on the literature that is summarized in Exhibits 2 and 3.

THE WITNESS: Yes, yes.

BY MS. STEIN:

Q Is there any other basis for your opinion regarding Waukegan Harbor?

A No.

Q Does your opinion regarding Waukegan Harbor assume that the environmental residues of PCBs in the Waukegan area, Ditch, the parking lot and the Harbor contain no contaminants?

A No. It assumes that the nature of the residues here are generally the same as the residues involved in the exposures of the Michigan sports fish eaters and the residents of the Triana, Alabama that was studied by Kreiss, et al.

Q Have you reviewed any animal studies involving

PCBs?

A No, I have not.

Q Are you aware of any studies involving the hypothesis that certain PCB congeners may present a different risk to human health than other congeners?

MR. FEATHERSTONE: Would you read that question?

(Question read.)

BY THE WITNESS:

A By different congeners, do you mean PCBs with different levels of chlorination?

BY MS. STEIN:

Q No, I am talking about --

MR. FEATHERSTONE: Isomers?

MS. STEIN: Isomers.

BY THE WITNESS:

A Isomers. No, I am aware of no such studies.

BY MS. STEIN:

Q Are you aware of any studies that deal with the question of whether degree of chlorination of PCBs may have an effect on the toxicity of those PCBs?

MR. FEATHERSTONE: We are talking about human studies?

BY MS. STEIN:

Q To humans.

A Yes.

Q What are those studies?

A There are several of them. One of them was a study by Fischbein, et al. and the second by Smith, et al. and to the best of my recollection, both studies found dermatitis, whose relationship was primarily to the level of higher chlorinated PCBs.

Q Are there any other --

A Pardon me. There was a third study by Marone, et al. and again, I believe it showed the same thing.

Q Are there any other studies attempting to differentiate potential health effects based on degree of chlorination?

A Not that I know of.

Q In your opinion, are PCB blood levels an accurate indication of the route of exposure in humans?

A No.

Q Are PCB blood levels an accurate indication of the duration of exposure to PCBs?

A The data that I have reviewed contradictory, Humphrey found relationships. Other authors whom I cannot recall at the moment did not.

Q Would you like to refer to either bibliography here?

A Yes, I would like to refer to one of my tables if I may.

Q Certainly.

A I'm afraid my tables don't deal with this specifically and I am afraid without reviewing the papers in detail, I wouldn't be able to tell you which of the studies found no relationship.

I believe that they existed, but I would simply have to examine in more detail than I have available here.

Q I have some of his studies here that I can let you look at if you need to. I don't have them all. I wasn't able to get some of them.

MR. FEATHERSTONE: You don't seriously propose taking the time to have him sit down and look at the studies and again to answer the question, do you? Couldn't you determine that by looking at the paper and seeing what that report is, Ms. Stein?

MS. STEIN: I would like to have him look at them and tell me which he recalls, if seeing the paper would help him recall, yes.

MR. FEATHERSTONE: Well, here is what we will do as a compromise gesture.

She says she wants you to see the studies

which I presume she will hand to you. Why don't you look at the study, don't take the time to read the study in detail unless you think it refreshes your fact memory that it refers to the point she is clarifying about. If you can identify the studies from the stack she is going to give you, I think the question was relating to no findings that blood level is an indicator of level of exposure, then single those out and show them to her, but we are not going to take the time to sit here and read them.

(Documents tendered to the witness by Ms. Stein.)

BY THE WITNESS:

A This one does not.

BY MS. STEIN:

Q That is the --

A Fischbein, et al.

MR. FEATHERSTONE: Let us go off the record for a second.

(Discussion off the record.)

MS. STEIN: We have agreed that during the break, Dr. Gaffey will review his studies that I have been able to obtain and look through them to see whether or not some of the ones that I have here are those to which he

referred regarding a negative finding with respect to a relationship of PCB blood levels, duration, exposure.

BY MS. STEIN:

Q Dr. Gaffey, are PCB blood levels an accurate representation of level of exposure to PCBs?

A Generally speaking, yes, in the sense that on the average, the greater the level of exposure, the greater the average of blood level PCBs will be in a group.

Q Do you recall the studies on which you base that opinion?

A The one that immediately comes to mind is Dr. Humphrey's Michigan study, I believe.

I believe that Dr. Fischbein also found similar gradient levels of exposure in the capacitor workers that he studied.

Q And PCB blood levels are an accurate indication of the last exposure to PCBs?

MR. FEATHERSTONE: I object to the form of the question.

BY MS. STEIN:

Q What is the length of time that has elapsed since the last exposure to PCBs?

MR. FEATHERSTONE: I object, lack of foundation.

BY THE WITNESS:

A No, they're not. My evidence is one of the tables in my paper in which I have looked at studies that measured people after exposures had changed or ceased and this is Table 2 in which we find four studies which we did before and after measurements after exposure had either ceased or been decreased. Two of the studies found declines in PCB blood level and two did not, so the results as far as information recently of exposure are contradictory.

BY MS. STEIN:

Q Dr. Gaffey, are PCB adipose tissue levels an accurate indication of the duration of exposure?

A I don't know.

Q Are PCB adipose tissue levels an accurate indication of the level of exposure?

A I don't know.

Q Are PCB adipose tissue levels an accurate indication of the recency of exposure?

A I don't know.

Q Is there an association between PCB blood levels and any clinical effects that you know of?

MR. FEATHERSTONE: Before you answer that, may I have the question back, please?

(Question read.)

BY THE WITNESS:

A Some studies of occupationally exposed populations have shown a correlation between chloracne and other dermatitis and blood PCB levels.

BY MS. STEIN:

Q That is the only health effect that shows such an association?

MR. FEATHERSTONE: Wait a minute. I object to that because he carefully limited it to blood levels of occupationally exposed workers and we have already been over this about the route of exposure playing a very significant role in chloracne and dermatitis. And he specifically described the difference with respect to between environmental exposure and occupational exposure.

MS. STEIN: I think we have apples and oranges here. I was asking about PCB blood levels and their association to effects.

MR. FEATHERSTONE: And Dr. Gaffey in his last answer identified an association or a possible association between PCB blood levels in plant workers and dermatitis or chloracne, and now our follow-up question says that is the only one. He has not gotten into that follow-up question yet, but in essence, you did not tie

in his answer where he limited blood tissue of workers in plants; in other words, occupationally exposed people.

MS. STEIN: I am not trying to discount his limitation. I am trying to find out whether there are any studies that he is aware of that shows an association other than the occupational workers in plants between PCB blood levels and health effects.

MR. FEATHERSTONE: Okay, that question phrased that way is fine.

BY THE WITNESS:

A There are two studies with contradictory results. One was the study by Kreiss, et al. in Triana, Alabama, which showed a positive association between hypertension and blood PCB levels, and the second was a study by Smith, et al. of fairly highly exposed capacitor workers that showed no such association.

BY MS. STEIN:

Q Do you have an opinion as to the validity of the Kreiss study?

MR. FEATHERSTONE: With respect to what?

MS. STEIN: With respect to its positive finding between PCB blood levels and hypertension.

MR. FEATHERSTONE: Finding or association, positive

association?

MS. STEIN: That is what I said, positive association.

BY THE WITNESS:

A I believe until there is confirmation in an independent study that this cannot be accepted as a valid association with PCB levels. This community study, although it did take extensive account of co-variables in a sense is an isolated finding, isolated finding not confirmed but investigated and in a sense refuted by another study of a heavily exposed population.

BY MS. STEIN:

Q By that you mean the Smith capacitor workers?

A Yes, and under those circumstances in my opinion the association found by Kreiss is not valid unless there is confirmation with another independent study.

Q Doctor, I believe you testified the Kreiss study was a community study and that that involved people who ate fish with PCBs in them. The Smith study, I believe you said, involved capacitor workers.

Can you compare studies that used different means of exposure; in other words, can the Smith study which involved capacitor workers exposed in the

workplace be taken as a refutation of the Kreiss study, given the differences in the studies?

MR. FEATHERSTONE: Do you understand the question, Doctor?

THE WITNESS: Yes, I understand the question.

BY THE WITNESS:

A I think it can because if the outcome that we were talking about was local outcome such as chloracne, it would be appropriate to say that it is very possibly a function of the route of exposure.

What we are looking at is a systemic condition and it is my opinion that the route of exposure is less important here than the blood levels that result from exposure, so I do think that these two cases are in effect measuring the same environmental variable.

BY MS. STEIN:

Q Do you know whether the Smith study took account of any confounding variables?

A No, I do not. It is not stated in the study.

Q Are PCB blood levels an accurate indication of possible liver malfunction?

MS. OLIVER: Liver what?

MS. STEIN: Liver malfunction.

BY THE WITNESS:

A I assume that by liver malfunction, you mean the levels of various enzymes, various liver enzymes as measured in various product samples.

MR. FEATHERSTONE: No, Doctor. She said PCB levels in the blood, are PCB blood levels an accurate indication of possible liver malfunction. That is what she said.

BY THE WITNESS:

A And in my answer, I am assuming that liver malfunction is measured by certain enzyme levels. If that is an appropriate assumption, I can answer.

BY MS. STEIN:

Q I will take it with that assumption.

A There was an association between the likelihood of finding elevated liver enzymes between that likelihood and the level of blood PCBs.

Q What is the basis for that opinion, Dr. Gaffey?

A The majority of the occupational studies I have reviewed have found this association.

MR. FEATHERSTONE: May I have the answer back, please?

(Answer read.)

BY MS. STEIN:

Q Dr. Gaffey, I believe that earlier you said your paper which has been marked as Exhibit No. 3 -- is

that correct?

A That is correct.

Q -- had been submitted to EPA, is that right?

A Made available to EPA.

Q Did you personally make it available to EPA?

A No. It was submitted as part of the Chemical Manufacturers Association submission.

Q In conjunction with some sort of regulatory proceeding?

A Yes.

Q What is that proceeding?

A I'm afraid I cannot tell you precisely. It is in connection with, I believe, the proposed rule-making with respect to PCBs.

Q Did you do that on your own or was it by contract with anybody?

MR. FEATHERSTONE: Wait a minute, what?

MS. STEIN: The paper.

MR. FEATHERSTONE: You mean write the paper?

MS. STEIN: Yes.

MR. FEATHERSTONE: Okay.

BY THE WITNESS:

A I did this on my own in response to a request from the American Chemical Society about a year and a

half ago, I think it was. The Society was holding a meeting and wanted to have a two-day session on epidemiology and someone from the organizing committee called me up, asked me to give some examples of occupational edpidemiologic studies and said they were particularly interested in chlorinated hydrocarbons.

At that time we had recently completed doing an in-house study of PCB exposures and I thought it would be appropriate to review some of the studies that had been done on PCB mortality.

I had broadened it out to include morbidity as well and the Chemical Society said they agreed and they would be willing to have a presentation made, so the original presentation was made at this New York meeting of the American Chemical Society.

It was, I believe as I say, approximately a year and a half ago.

BY MS. STEIN:

Q Did you ever work with anyone at Ecology in Environment, EIE, on that paper?

A No.

Q You said you recently completed an in-house study on PCB exposure.

A Well, it wasn't recent. It was at about the

time that I was asked to give this presentation to the Chemical Society which was about a year and a half ago.

Q Is that the Zack papers in preparation --

A That is correct.

Q Has that ever been made public?

A It has not been submitted for publication, but it is now being revised by the two authors, the revising being to update the references after which it will be submitted for publication.

MS. STEIN: Can I make a request that when that is made available --

MR. FEATHERSTONE: You mean available for publication? You want a copy or when it is submitted for publication you want a copy of it?

MS. STEIN: Yes, because it is one of the references, resources and references to Dr. Gaffey and I have not been able to get it.

MR. FEATHERSTONE: It is not surprising. It hasn't been made public.

MS. STEIN: So it is a little hard for me to ask him about it.

MR. FEATHERSTONE: I will write this down.

BY MS. STEIN:

Q Dr. Gaffey, why don't you take a copy of your

paper in front of you because I am going to be asking you some questions about it.

On the first page, the summary, you state:

"Alterations in liver and fat metabolism were found in most studies that examined these functions, but there was no clinical illness associated with these alterations or with level and duration of exposure to PCBs."

A Yes.

Q Can you tell me what you meant by clinical illness on that first page?

A Clinical illness would be something that a doctor would diagnose as an illness that would require treatment.

Q Can you give me some specific examples?

A Dermatitis, rheumatism, diabetes, stomach ulcer.

Q Tell me if this is correct. Is it fair to paraphrase that sentence as saying that there were chemical alterations in individuals, in their systems, that did not manifest themselves in terms of something requiring treatment by a doctor?

A Yes.

Q Is the term clinical illness a term of art in epidemiology?

A It is a medical term and as I have used it here, I have essentially quoted it from several of the papers that I read, including that of Smith and that of Hasegawa, a Japanese article.

Q Do you know whether clinical illness was looked for in all of the papers that you reviewed?

A They were not looked for in all the papers that I reviewed.

Q Do you recall which papers they were not looked for in?

A I can tell you which ones they were looked for in.

Q Why don't you do that.

A That is in my Table 4, essentially the studies that looked into the question of clinical illness and symptoms in the column headed Symptoms and Illness and opposite study. If there is an entry of N in there, that means they were looked at and they found nothing. If there is a Y, that means they looked and found something. If there is a blank, that means either they didn't look or they didn't report whether they had looked or not.

Q By the way, you mentioned earlier a South

Carolina Department of Health and Environmental Control. It is listed as a news report. Is that something published?

A The only information we had was that it was a news report from the South Carolina Department of Health and Environmental Control. We were aware of no other published accounts from there.

Q Do you know whether that was a peer reviewed document of some sort?

A I am virtually certain it was not.

Q Do you have a copy of that?

A No, I don't.

Q Have you in fact read it?

A I have read a quote of the conclusions in that article.

Q And is that quote from the conclusions a statement, "that there is no evidence of physical harm resulting from working with PCBs"?

A Could you tell me what page?

Q Yes, Page 11.

A Yes. That is the quote. You will notice that that study and a second study which was also rather non-specific are not really considered in any substantial way in my review.

The South Carolina and the one by Kappanen and Kolhol are both non-specific; in effect, they say we found nothing, but since they weren't specific, I didn't include them in my analysis or in the other tables in the back.

Q Inother words, you are not sure what they are even looking for in those?

A That's right. They say they didn't find anything, but that they looked and in order not to find anything, this is not apparent from reports that are available.

Q Are there specific clinical tests that are associated with alterations in liver and fat metabolism?

A Not that I am aware of.

Q On Page 2 of your report, Dr. Gaffey, the second sentence of the first paragraph states:

"A study is considered 'epidemiologic evidence' if it measures, directly or indirectly, the differences in the risk of ill health among populations with different exposures to PCBs."

Can you tell me what you mean by measuring something directly?

A If a study actually looks at the percentage of individuals who had some sort of ill health and does

this for groups of individuals with different exposures, then I would say that that study measures directly.

What has happened there is a different type of epidemiologic study called the case control study which does not measure directly. Instead of looking at percentage of illness in different exposure groups, it looks at the percentage of exposure in different illness groups. This is in a sense backwards from the kind of study that is represented here.

Supposedly this can be used to evaluate differences in risk but not directly. Essentially an arithmetic observation has to be taken in order to arrive at the conclusion. That is what I mean by directly.

Q You are talking about case control studies here?

A Yes, that is right.

Q That same sentence talks about ill health. Is ill health used in that sentence synonymously with clinical illness?

A It is synonymous with clinical illness or death. I beg your pardon. It is synonymous with clinical illness.

Death or self-reported illness, all of these things were examined in one or the other of the studies that is looked at.

Q The last paragraph of that page says:

"Second, there are studies of the relationship between exposure to PCBs and the resulting body burden of PCBs in serum or adipose tissue. Strictly speaking these are not epidemiologic studies since they do not deal with health effects."

Can you explain why you said that the studies referred to in the first sentence are not strictly speaking epidemiologic studies?

A Because you measure the relationship between the level of PCBs in the environment and the level of PCBs, for example, in blood. This is not a measure of ill health. It is a measure of the extent to which the environmental exposure is reflected in the body burden, but there is no measure of ill health here.

So by definition an epidemiologic measure of ill health, when you are looking at the relationship between level of PCB in two different places, one outside the body and one inside, either of these is a measure of ill health which is why I say those are not epidemiologic studies. I point out that they are useful studies, but they are not of themselves measures of ill health.

Q As you defined it earlier?

A As I defined it.

Q On Page 4 of your study, there is a reference to a paper by Meigs.

A Yes.

Q In that paper, you report that, "Seven of fourteen exposed workers developed chloracne, but liver function tests were normal in six of these, with some borderline abnormalities in the seventh."

Do you know whether Meigs looked for any liver function abnormalities in the seven workers who did not have chloracne?

A I do not know.

Q On the bottom of Page 4, running over to Page 5, there is some discussion of Yusho manifestations and you report that, "Six years later, many patients still reported such symptoms as headache, stomach pain, numbness of the extremities, joint pain and respiratory symptoms."

Do you attribute any significance to the fact that patients were still reporting symptoms six years after the event of ingestion?

MR. FEATHERSTONE: Significance to what?

MS. STEIN: From an epidemiologic standpoint.

BY THE WITNESS:

A Yes, I do, but not from the standpoint of exposure to PCBs.

BY MS. STEIN:

Q Why is that?

A For four reasons: The first is that the Yusho incident was a massive poisoning by the ingestion of some substance and no matter that it was the amount was so great that these people by the thousands became very sick. So no matter what the exposure was, it was obviously immensely greater than what would be found in the environment.

The second thing about the Yusho incident which was not apparent at the time it occurred in 1968 but became apparent as lab techniques improved was the large concentration of polychlorinated dibenzofurans in the PCBs that were ingested by the Yusho victims.

Number three is in almost a decade after in tissues of Yusho patients, one of the principal Japanese investigators, Dr. Kuratsune, reports that what is remarkable is that in livers of Yusho patients, the level of PCBs is about equal to what one would find in the general population after this length of time, but the level of polychlorinated dibenzofurans is much, much greater than what would be found in the general

population and finally their opinion that this is not a straightforward measure of PCB exposures is shared by Dr. Humphrey and Dr. Kimbrough.

Q You say that that opinion is shared by them. You found that by reading their depositions, is that correct?

A Yes.

Q I believe you said that ten years later tissues that were examined. Is this liver tissues that were examined?

A Yes, in particular my statement was about liver tissue.

Q Do you know how long the retention time is in liver tissues for PCBs?

A No, I do not.

Q So it is possible that some of the PCBs might have been eliminated in ten years?

A Yes, it is possible.

Q Do you know anything about the retention time of dibenzofurans in human tissues?

A No, I do not.

Q Dr. Gaffey, on the bottom of Page 5 of your paper, there is some discussion about deaths among Yusho patients, and in the middle of that last para-

graph on the bottom of Page 5, you state:

"First, after the original incident, the criteria for diagnosis of Yusho had been changed, so that it is impossible to determine the denominator which produced this number," referring back to the percentage of deaths, I believe, is that correct?

A Back to the 51 deaths.

Q Could you tell me what the original Yusho criteria were and wnen they changed?

A No, I cannot with any degree of specificity, but one of the original Yusho investigators in reviewing the history of it, I believe it was Dr. Kuratsune in a book that was edited by Dr. Kimbrough, states and I cannot quote him exactly, but it was after such and such a date, we decided that this kind of symptom also indicated Yusho. And so the number of people who were identified as being Yusho patients having Yusho symptoms got larger.

We don't know of these 51 deaths, out of these definitions of Yusho they came or out of all of them, perhaps. So we have no idea here, first of all, whether 51 deaths is too many or not, and given the deaths, we don't know whether all of the deaths were found and even if they were, we don't know the percentage

of cancer deaths. Maybe 35 is too large because that can only be determined if you look at what would be expected in a group of people in the same distribution by age.

Since the age distribution was not made, we don't know whether 5 percent was too much. It says 35 percent was greater and the percentage exceeded that of the prefecture in which the deaths occurred. But we don't know anything about the date of deaths in the prefecture so the type of study that is being done here is one called proportional mortality study.

But in doing that, one makes a distribution or attempts to that you didn't have. First, here the problems are manifold. Here, we don't know whether all deaths were as certain and if they were, we don't know whether 35 is too many because we don't know the total, and regardless of those we don't know if 35 is the cancer deaths because we have not adjusted for age, and actually there is one more problem because a determination was made about a decade after the incident.

Considering the latent period for cancer, that is a little bit short for detecting cancers that might result from the exposure and we don't know that these deaths occurred ten years afterwards. Some of them

may have occurred two or three years afterwards. No details are given in the report of these, unfortunately.

Q On the basis of all these difficulties, did you draw any conclusions about the relationship of Yusho disease and the oil ingestions to the risk of cancer?

A I cannot, but I think it is also relevant to the issue of PCB exposure for the reasons that I stated in connection with the dibenzofurans and the confusion that exists there.

Q Is there some sort of standard latency period for cancers?

A It varies, but most epidemiologists would agree that cancer arising from an occupational cause would probably not show up for between 15 and 25 years after the original exposure.

Q 15 and 25?

A In some cases, some of the asbestos cancers can take up to 40 years, and in the other extreme some of the cancers caused by heavy radiation, for example Hiroshima, begin to show up as quickly as five years. But that is the only case where the latent period has been observed to be that short.

Q Are you saying that some of these latency periods are cancer-specific?

A They do seem to vary with the cancer and seem to vary apparently to some extent with the agent. Apparently there is some indication that radiation-induced cancers have a short latency period than, for example, drug or chemically-induced cancers.

Q What is the relevance of an age adjustment or lack of age adjustment as you have described here at Page 5?

MR. FEATHERSTONE: Wait a minute. Are you referring to specifically the bottom of Page 5?

MS. STEIN: Yes, where Dr. Gaffey says there is no adjustment for age appeared to have been made in the above comparison. I am trying to get at the significance of that.

BY THE WITNESS:

A Percentage of deaths that are due to different causes varies by age. In young children, cancer is an important cause of death because they don't die of anything else.

In young adulthood among males, for example, leading cause of death is accidents. Secondly, second leading cause is, I believe, suicide. In older ages,

the important cause of death is, of course, cardiovascular disease. So if you have a group of people, half of whom had died from accidents, which this was, much would depend on whether they were 20 years old or whether they were 60 years old, and the increasing problem here, when we see 35 percent of these deaths were due to cancer, that is dependent on that age group, as to whether there was any other cause of death.

BY MS. STEIN:

Q Are there statistics published somewhere that set forth these adjustments for age and --

MR. FEATHERSTONE: Are you speaking abstactedly?

MS. STEIN: I am talking about a general proposition.

MR. FEATHERSTONE: No, I don't know whether we were talking about the Japanese statistics --

MS. STEIN: No, I am talking about American.

BY THE WITNESS:

A Published data on mortality, certainly in the United States and I believe in Japan are available and in a great deal of detail by age, weight, sex and cause. That is sufficient data to enable this kind of adjustment to be made. However, the data may not be available for a geographic area such as an individual prefecture

in Japan, I don't know. They would be available for a counting in the United States, but whether that would apply or not in Japan, I don't know.

MS. STEIN: Let's take a short break.

(Brief recess had.)

BY MS. STEIN:

Q During the break, Dr. Gaffey, did you review a number of articles to see whether or not they refreshed your recollection as to those studies that did not report an association between PCB blood levels and duration of exposure?

A Yes, I reviewed the studies that you gave me and was unable to find one that referred to this.

MS. STEIN: The names of the articles that were given to Dr. Gaffey for his review are:

1. Use and Health Effects of Aroclor 1242, A Polychlorinated Biphenyl, in an Electrical Industry - Ouw, et al.;
2. Clinical and Metabolic Abnormalities associated with Occupational Exposure to Polychlorinated Biphenyls (PCBs) - Chase, et al.;
3. Occupational Exposure to Polychlorinated Biphenyls in Electrical Workers, I. Environmental and Blood Polychlorinated Biphenyl Concentrations -

Maroni, et al.;

4. Decrease in Vital Capacity in PCB-Exposed Workers in a Capacitor Manufacturing Facility - Warshaw, et al.;

5. Metabolic Consequences of Exposure to Polychlorinated Biphenyls (PCB) in Sewage Sludge - Baker, et al.;

6. Present State of Yusho Patients - Harukuni Urabe, et al.;

7. Alterations in Drug Metabolism in Workers Exposed to Polychlorinated Biphenyls - Alvares, et al.;

8. The New England Journal of Medicine, (Letter to the Editor), Dated January 13, 1977;

9. The New England Journal of Medicine, August 19, 1976, Melanoma After Exposure to PCBs;

10. Relevance of Epidemiology to Policies for the Prevention of Cancer - Sr, Richard Doll;

11. Clinical Findings Among PCB-Exposed Capacitor Manufacturing Workers - Fischbein, et al.

MR. FEATHERSTONE: The only other thing I would like to put on the record, Ms. Stein, is I will make a statement and if I am wrong point it out, that the articles and documents you gave to him are not all of

the documents and articles which have appeared in the references to his paper.

MS. STEIN: That is correct. I have been unable to obtain all of them.

BY MS. STEIN:

Q Dr. Gaffey, on Page 6 of your report, you referred to a recent reanalysis of the cooking oil and of the estimated intake by the patients.

Does that recent reanalysis refer to what is listed as your reference 8 farther down in that same paragraph?

A I believe so, but it should refer to the book edited by Dr. Kimbrough.

MS. OLIVER: And it does.

THE WITNESS: Yes.

BY MS. STEIN:

Q That same sentence talks about your current determinations of PCQs in blood and other tissues of Yusho patients have shown levels similar to that of PCBs.

Do you recall what the other tissues were that were examined?

A No, I do not.

Q Do you recall how long after the Yusho incident

these determinations were made that are referred to here in the last paragraph?

A I believe it was nine years afterwards.

Q But that would be specified also in that book, Reference 8?

A Yes, yes, it would.

Q On Page 8 of your paper in the first full paragraph which begins:

"The measure of body burden," you say, "analytic methods have varied over time and among investigators."

Can you expand on that statement, please?

A First of all, this is an area somewhat out of my expertise, but certainly the sensitivity of analyses for PCBs has improved and since PCBs are a combination of many different congeners and many different levels of chlorination, different methods have varied in their ability to determine different ones in this complex.

As we get to more recent times, these things have improved and become more consistent. Another thing I have been told is that past analytic methods are subject to contamination which may vary from laboratory to laboratory, so that it becomes difficult to compare, especially in the older studies, values

that were found by two different investigators in two different studies.

Q By contamination, are you talking about dirt on the laboratory equipment?

A Essentially that, yes. There are PCBs, I am told, in cigarette smoking.

MR. FEATHERSTONE: You mean residual PCB contamination that is being analyzed in the laboratory?

THE WITNESS: Different sources other than what is being analyzed, yes.

BY MS. STEIN:

Q How does that variation in methods and on an investigator's specific opinion affect your opinion about the validity of any of the studies that you reviewed for this paper?

A Only in the sense that some of the relationships that were found with blood PCBs may in fact be more clearcut than was indicated by the actual data analysis.

Q On the last sentence in Page 10 of your paper, there is a suggestion that this, meaning the relationship of PCB burden to duration of exposure, to "studies not being consistent may be due to the confounding effects of age and sex, or to differences in the metabolism of

high and low chlorinated PCBs, with the higher PCBs being more likely to accumulate in adipose tissue."

Can you tell me the diference in metabolism of high and low chlorinated PCBs?

A Only that according to some authors such as Maroni, the low chlorinated PCBs appear to be metabolized and/or eliminated more rapidly than the high chlorinated PCBs.

Q Do you know whether Maroni or anybody else has examined the differences in metabolism based on the isomer of PCB?

A Not so far as I am aware.

MR. FEATHERSTONE: You are talking about human metabolism?

THE WITNESS: I assume that we are talking about human metabolism.

MS. STEIN: Yes, human metabolism because Dr. Gaffey said he hadn't reviewed any animal studies at all.

MR. FEATHERSTONE: I am making sure that was the intent of your question.

BY MS. STEIN:

Q Then the places where higher PCBs being more likely to accumulate in adipose tissue, what is the

basis for that phrase?

A I put this in the sentence beginning with that suggestion because Maroni and his colleagues state it, in effect, that this is the case.

Smith, on the other hand, says almost the opposite.

About a quarter of the way down that page, "No evidence either to support or refute different accumulation kinetics in humans for the lower and higher chlorinated biphenyls."

However, Maroni, et al. appeared to produce even that perhaps the higher PCBs are retained. Smith says he has no such evidence.

Q Did Maroni or Smith or anyone else look at the accumulation in tissue other than adipose tissue?

MR. FEATHERSTONE: Well, blood is a tissue. You are excepting blood as well?

MS. STEIN: I am not including blood.

BY THE WITNESS:

A Hardly anyone looked at the studies in adipose tissue. Smith did not, Maroni, et al., I believe, did not.

What they did was they looked at blood and they conjectured that the explanation for their blood findings was that the higher PCBs being stored

in tissues and released, but to the best of my recollection, they did not look at adipose tissue.

BY MS. STEIN:

Q Were you aware of any studies where somebody looked specifically at the accumulation of higher versus lower chlorinated PCBs in adipose tissue?

A No.

Q On Page 11 in the third paragraph, there is reference there to "Kappanen and Kolhol."

Now, these were the ones that you said you had only limited information on in response to a couple of earlier questions, is that correct?

A That is correct. The Kappanen and Kolhol one looked at employed people, some occupation, I believe they looked at three.

MR. FEATHERSTONE. Dr. Gaffey, she didn't ask for an elaboration on the test. She asked if you had limited information.

BY THE WITNESS:

A I had limited information.

BY MS. STEIN:

Q What was the limited information that you had available to you?

MR. FEATHERSTONE: For which test?

MS. STEIN: For both of these two studies that are referred to in this paragraph.

MR. FEATHERSTONE: In answering that question, make specific reference to which test you are referring to so we know what the limited information is with respect to the test.

BY THE WITNESS:

A Study of the Kappanen and Kolhol, the information available was that they were looking at three different groups of people, three different levels of exposure. The study concluded simply that all participants in the study were in good health with no further information.

In the second study from South Carolina, in a study of only of the exposed workers, the author states there is "no evidence of physical harm..." There was no further information given beyond that which I have indicated on either of those two studies.

BY MS. STEIN:

Q Based on the limited information available to you with respect to both of those studies, can you draw any kind of conclusion at all about the health effects that may result from exposure to PCBs?

MR. FEATHERSTONE: Based only on those two studies?

MS. STEIN: Based only on those two studies.

BY THE WITNESS:

A Based only on those two studies, I could draw a general conclusion that there was in all probability no extremely serious effect, but I could not be any more specific on that based on these two studies alone.

BY MS. STEIN:

Q With respect to the first of those two studies, the Kappanen and Kolhol, was there any indication of the sample size that was made available to you?

A Yes. There were three samples of people with different exposures and my recollection is that there were less than a hundred people in each sample, but I can't remember any more clearly than that.

Q With respect to both of those studies, do you know whether there were any control groups that were looked at by the authors.

A In the first of the studies, these were sort of the controls because within the study group there were three different levels of exposure.

In the second, South Carolina study, there were partial controls in the sense that out of 32 workers studied, 10 of them stated to have regular exposure to PCBs.

Q Do you know about the remainder of the group?

A No, I don't.

Q On Page 12 at the top, you refer to Hasegawa, et al., and say:

"The average blood PCBs in the workers was 370 parts per billion. However, the authors state that skin complaints were unrelated to blood PCB levels and appeared to be due to skin contact."

Do you know whether the authors of that report looked for any other kind of measure of exposure to PCBs to associate the skin complaints to?

A No, I do not.

Q In the last sentence of that same paragraph, you state:

"The complaints were not related to blood levels of PCBs, and virtually disappeared within a year after exposure had ceased."

That is essentially referring to the Hara, et al., that is the subject of the previous sentence?

A Yes.

Q In the study done by a person whose name is spelled O-u-w, there were referred to, "Reported 14 cases of dermatitis, eye irritation or burning sensations on the skin out of 34 exposed workers, where air

levels of PCBs ranged from 0.32 to 2.22 mg per liter."

Do you know whether the investigators in that study looked at anything other than dermatitis, eye irritation or burning sensations on the skin?

A They didn't state.

Q Do you know whether they had any kind of control group?

A They did not.

Q Do you know whether they tried to associate those effects with anything other than blood levels in the studied population?

MR. FEATHERSTONE: Wait a minute.

BY MS. STEIN:

Q (Continuing.) In terms of body burden.

MR. FEATHERSTONE: If you are referring to -- objection if you are referring to the two sentences here. It doesn't state anything about blood levels, that I can see. It talks about air levels.

MS. STEIN: The next sentence after that talks about complaints appear to occur more often in terms of blood levels.

MS. OLIVER: It doesn't say association.

BY MS. STEIN:

Q To your recollection, did those authors

associate dermatitis, eye irritation or burning sensations on the skin with PCB blood levels?

A Yes, they stated these things with more frequency with those higher PCB blood levels.

MR. FEATHERSTONE: Ms. Stein, when you are using the word association, are you implying a statistically significant association or any association, statistically significant or not?

MS. STEIN: No, it doesn't have to be statistically significant.

MR. FEATHERSTONE: When you use the word association as you have understood it, how have you understood it?

THE WITNESS: To mean not necessarily statistically significant.

MR. FEATHERSTONE: Okay.

BY MS. STEIN:

Q Dr. Gaffey, do you know if those same investigators in that study searched for an association between the observed effects and body burden other than the blood levels?

A They did not state that they did.

Q On Page 14 of your paper, Dr. Gaffey, under the topic of Liver Function, you report on Hasegawa,

et al. finding mild disturbances in exposed workers which they did not consider to be clinically significant.

Can you tell me what you mean by the phrase "clinically significant" in that sentence?

A Those two words are, to the best of my knowledge, a quote from them which was originally in Japanese, a summary which I read in the NIOSH criteria document, but I would judge clinically significant means not significant of any clinical illness.

Q As previously defined?

A Yes.

Q Then on the summary on the bottom of Page 14, you say:

"Five studies of the nine found some mild liver function abnormalities, none of which were associated with any measurable adverse effects."

By that, is that synonymous with no clinical illness?

A No, it is a broader term than that.

MR. FEATHERSTONE: The term you are referring to is measurable?

THE WITNESS: Measurable adverse health effects which included several reports by people of things which might or might not be brought to the attention of

the physician; for example, it included in the two non-occupational studies, included questions like, "Have you had a weight change in the last year?"

So it is a more inclusive term than clinical illness.

BY MS. STEIN:

Q On the top of the page, Page 15, there is a reference to Fischbein, et al. in the study of capacitor manufacturing workers and you say that:

"It was noted that 'there was a paucity of abnormal results in the biochemical studies.'"

By this do you mean that the authors are saying there were no effects?

A There were fewer abnormal results than one would have expected in the general population is my interpretation of what they had said.

Q Was that limited to one aspect of that quote from Fischbein, was that limited to one particular aspect of their investigation or was that overall with regard to the findings?

A My recollection is that they are talking about biochemical studies of liver function, but it may be broader than that.

Q Under the heading Fat Metabolism on that same

page, the last sentence of the discussion on that subject says:

"Even if PCB exposure has some effect on fat metabolism, it appears to be without any apparent clinical significance."

First of all, can you tell me what you meant there by clinical significance?

A I would expect that if you were looking for something that would lead you to suspect clinical illness, you would say, well, you would worry about some consistent effect. If controls always went up, you would have to ask yourself if this meant anything in terms of clinical illness.

In this situation, the only thing I can say about clinical significance is that everything possible happened to them with equal frequency.

Q Is that based on the studies that you reviewed?

A Yes.

MR. FEATHERSTONE: When you said everything possible happened to them, the them refers to --

THE WITNESS: Control levels in the studies.

BY MS. STEIN:

Q On the bottom of Page 15, you talk about "five studies of blood chemistry," and state:

"None of them report any relationship of blood chemistry to PCB levels."

What were the parameters that were used to define this blood chemistry that these investigators were looking for?

A They were looking for things like hemoglobin level, count of white blood cells, count of red blood cells, measurements of volume of red blood cells and probably some other parameters that I cannot recall.

Q There was not any of these that showed any abnormalities at all, is that correct, is that a correct interpretation of what that sentence is?

A No abnormalities related to PCB levels.

Q Were there any abnormalities at all reported?

A I don't recall.

Q On Page 17?

A May I clarify something on Page 16 that may be somewhat misleading?

Q Sure.

A At the top of Page 16, there is a reference to diastolic blood pressure and blood PCBs and here I say that Kreiss, I gave the findings of Kreiss, and I say there is no control group and this is the only investigator who reported this finding.

Well, in fact, although in putting together this review I had a copy of a paper by Smith, et al., I didn't have the final copy that was submitted for publication and the final copy is the one that does include their work on blood pressure. So if there is an omission here, it is due to the fact that I had at the time an earlier version of Smith's paper.

Q Does that clarification in any way change the conclusion that you reached:

"Since Kreiss, et al. are the only investigators to report this finding, its significance is not clear at this time"?

A It further diminishes the significance because we have new results in an independent look that does not confirm what Kreiss found.

Q In the middle of Page 17, you write:

"The weight of evidence, as Smith, et al. conclude, is that no studies to date 'have shown that occupational exposure to PCBs is associated with any adverse health outcome, to be distinguished from demonstrable subclinical biochemical alterations.'"

I guess I'm trying to find out in light of the testimony earlier regarding chloracne, how that squares with this statement here on Page 17.

MR. FEATHERSTONE: Are you asking Dr. Gaffey to square his testimony with the statement as quoted from Smith?

MS. STEIN: I am asking Dr. Gaffey to square his testimony with the entire sentence there.

BY THE WITNESS:

A My testimony agrees with that with the exception of dermatitis and possibly chloracne which other investigators have found in some cases to be associated with PCB.

I think that this particular section deals with symptoms as opposed to dermatitis and I wonder if we went back to the section on dermatitis whether we might not be able to see whether Smith did not indeed --

MR. FEATHERSTONE: Dr. Gaffey, I think all you have to do at this stage until she asks you to do something more is to point out to Ms. Stein that that sentence does not fall within the portion of documents that relate to chloracne and dermatitis. You have proven that out, I believe.

THE WITNESS: This is true.

BY MS. STEIN:

Q Dr. Gaffey, can you tell me about the Zack

study that is in preparation?

MR. FEATHERSTONE: Can you be more specific?

MS. STEIN: I cannot because I don't know what it is. I have never seen it.

BY MS. STEIN:

Q What can you tell me about the Zack study in preparation?

MR. FEATHERSTONE: Do you want to know numbers, do you want a chronological step by step development of that research project? Can you tell me what it is you want?

BY MS. STEIN:

Q Study design, whether it is hypothesis generating or hypothesis testing, what they are looking at, what the results are, what they accumulated to date.

MR. FEATHERSTONE: It strikes me that you know enough now to list six or seven things, so why don't you ask it question by question because he is not going to go into a narrative question on that.

You can ask what it looks for and break it down into separate questions just the way you have started to.

MS. STEIN: I don't really care.

BY MS. STEIN:

Q Dr. Gaffey, can you answer the first way or would you prefer it broken down?

MR. FEATHERSTONE: The choice is not his.

MS. STEIN: The choice is that I asked the question in a certain way and if he doesn't understand it, he can tell me that and I will do it, but, Bruce, frankly it is just taking much more time than it is worth at this point.

MR. FEATHERSTONE: Elizabeth, you are not going to ask a question, "What can you tell me about the Zack study?"

Do you have a specific question like what is the design protocol, I will let him answer that.

What did you find, he will answer that.

Is it hypothesis generating or hypothesis testing, I will let him answer that. But we are not going to sit here and entertain at 4:05 in the afternoon, after a whole day of this, a wide open question like that.

MS. STEIN: Are you instructing him not to answer the question?

MR. FEATHERSTONE: Absolutely. It is --

MS. STEIN: Dr. Gaffey, when --

MR. FEATHERSTONE: Just a minute, Elizabeth. I was not finished talking.

What I started to say when you suddenly interrupted is it is my duty to instruct the witness not to answer the question, but I did not get it out, so now you can ask the question specifically.

MS. STEIN: Certify the question.

MR. FEATHERSTONE: I would suggest if you intend to take that matter before Judge Getzendanner and that you call her chambers now because you can ask and get information you want by asking specific questions and we are not going to send Dr. Gaffey home at the conclusion of his deposition and have you running before Judge Getzendanner and have you say, "Your Honor, I want permission to ask this wide open question --"

MS. STEIN: It is not that wide open a question. It relates to one study.

MR. FEATHERSTONE: I am still talking, Elizabeth.

-- when you get that question properly posed as a specific question.

BY MS. STEIN:

Q Dr. Gaffey, what do you know about the Zack study?

MR. FEATHERSTONE: Doctor, tell her what was looked

at, what you looked for and what you found and if there were conclusions, what the conclusions were; those four things.

BY THE WITNESS:

A We identified everybody from plant records who had worked in the production of PCBs at the plant that was involved in the production of these from between 1945 and 1965, and followed them to the end of 1977.

We were looking for a general pattern of cause of death. It was a hypothesis-generating study in the sense that although we were interested in excess cancer mortality, we had no preconceived idea about what we might or might not find.

I do not recall what the total number of deaths were. We found nonstatistically significant excess in lung cancer deaths; concluded that the total number of deaths in the study was inadequate based on that study alone to come to any conclusion one way or the other.

BY MS. STEIN:

Q Dr. Gaffey, what confounding variables if any were taken into account in that study?

A The usual ones in such a study; age, race, sex,

date of birth and duration of employment.

Q Was smoking taken into account?

A No, it was not.

Q Was alcohol consumption taken into account?

A No.

Q What is the latency period for lung cancer?

A I cannot answer precisely, but I would estimate that it would be from 15 to 30 years.

Q Do you think that the time that had elapsed up to the end of 1977 was sufficient for the latency period to have matured, if you will?

MR. FEATHERSTONE: I object to the form of the question.

BY MS. STEIN:

Q (Continuing.) With respect to the cancer?

A Yes, because of the average duration of follow-up in this population which was approximately 20 years.

Q 20 years after first exposure?

A Yes.

Q In mortality studies, do you look at the date of first exposure in trying to calculate the latency period for cancer?

A Yes.

Q Is there any follow-up work going on in that

study?

A No, there is not.

Q Were there any other excesses of cancer?

A Not that I recall.

Q In your opinion, Dr. Gaffey, is the presence of consistency required in determining causality of cancer?

A You mean in epidemiology studies?

Q That is right.

A Yes.

Q Can you tell me the basis for your opinion that the presence of consistency is required?

A There are two bases: One is the logical one that if a given substance causes a particular cancer in one situation, it ought to cause it in another, but more formally the International Agency for Research in Cancer a few years ago published a list of the guidelines because of their concern of interpreting epidemiology studies.

This list of criteria for inferring carcinogenicity from epidemiology studies is essentially the list of the criterion I gave when you asked me what constituted a positive study.

Q Have you concluded that PCBs are definitely

non-carcinogenic?

A Yes, I have.

Q Is that based on the literature that you have reviewed?

A It is based in particular on the mortality studies listed in my review.

Q Are mortality studies based in large measure on information in death certificates?

A Almost all of them are based entirely on death certificate information.

Q Is death certificate information generally regarded as reliable as to the cause of deatn?

A In the case of cancer, it is generally regarded as being more reliable than in the case of other conditions, such for example as heart disease. However, the crucial question is not whether death certificate information is reliable. The question is whether the reliability is of the same degree as the national statistics to which they are compared.

In other words, if one were able to get a more reliable cause of death than a death certificate, the data would then no longer be comparable with national data which are themselves based on death certificates.

Q Are you aware of any incidence studies involving

cancer from exposure to PCBs?

A No.

Q Incidence as opposed to mortality studies.

A No, I am not aware of any.

Q Did the Zack study follow up people who had left employment?

A Yes.

Q Is it fair to state, Dr. Gaffey, that it is your opinion with respect to the Yusho victims in Japan that the persistence of symptoms that is mentioned on Pages 4 and 5 of your paper are entirely attributable to dibenzofurans or polychlorinated quaterphenyls?

A Or to other contaminants that may have existed in those PCBs.

MS. STEIN: Let me take a couple of minutes. I don't have too much more.

(Brief recess had.)

BY MS. STEIN:

Q Dr. Gaffey, who are Drs. Zack and Musch, M-u-s-c-h?

A It's pronounced Musk.

Mrs. Judith Zack at the time this study was written was one of my staff. Dr. Musch, then Mr.

Musch, was a medical student who worked for us for a couple of Summers and assisted here in the data collection for the study.

Q How many people are on your staff?

A I have at the present time, three professionals, one of whom is on maternity leave; two clerks and one secretary.

Q What are the three professionals?

A Two of them are epidemiologists at the Master's level as was Mrs. Zack. The third is a person we call data management technician, who takes care of the details of acquiring data from our plants when a study has to be done.

Q Does your department do studies, only epidemiology studies or Monsanto plants?

A That is correct.

Q With respect to the Zack and Musch studies, what plant was that study carried out in?

A That was carried out in the W. C. Krummrich Plant in East St. Louis.

Q Is there any kind of comparable study being carried out at any of the other facilities with PCBs manufactured by Monsanto?

A No.

Q Do you know why that is?

A I am not sure there were any more facilities, but I am not certain because the manufacture took place at the time before I came to Monsanto.

Q With regard to your review of the epidemiological literature on PCBs, did you in any way examine the qualifications or credentials of any of the authors?

A Not in any systematic way. Some of the authors were known to me, but no, I did not in any systematic way examine them.

Q Who are the authors that were known to you?

A Dr. Smith, Dr. Brown. I believe there was one other that was known to me. May I look at those references?

Q Sure, feel free to look at the list.

A And Von; Von, Brown, Fischbein, Kimbrough -- well, she strictly speaking was not an author. She was among my references, but also Smith, Warshaw and Zack.

Q And with respect to those seven people that you have just mentioned, were you satisfied that they had acceptable credentials to carry out the work that is this subject of the references?

A Yes, I am satisfied.

Q And with respect to the other authors, do you

have any opinion with respect to their credentials?

A Only that many of them have academic affiliation that would suggest their credentials have already been reviewed and to the best of my knowledge, all the journals listed here are ones that are peer reviewed journals.

Q Have you ever had your deposition taken before, Dr. Gaffey?

A Yes.

Q In connection with what matters?

A A suit in the matter of styrene exposure in which Monsanto was one defendant.

Q Any other occasions that you have had your deposition taken?

A In connection with a suit concerning a chemical spill in Sturgeon, Missouri.

Q What was the chemical?

A It was one of the chlorophenols. I'm not sure which.

Q Chlorophenols?

A This incident happened before I came to work for Monsanto, so my deposition was of necessity somewhat scanty.

Q Had you ever had your deposition taken other

than the two times that you have just mentioned?

A There were actually three times: In connection with the Sturgeon spill, my deposition was taken twice, equally scanty both times.

Q Have you ever testified at trial?

A No, I have not.

Q Have you ever been qualified as an expert witness in any judicial proceeding?

A No.

Q Have you ever given testimony regarding PCBs before?

Strike before.

A No.

MR. FEATHERSTONE: Wait a minute. Strike before, that would include his deposition today. You are not --

MS. STEIN: Okay.

MR. FEATHERSTONE: I mean he has given testimony regarding PCBs today.

BY MS. STEIN:

Q Okay, other than today. I thought I got it in the depositions.

A No, I have not.

Q Dr. Gaffey, I am going to refer you to Page 19 of your paper. I will refer you to your discussion of

the Brown and Jones study.

A Yes.

Q Can you tell me what the basis is for the statement that:

"Since U.S. population rates were used as a basis for comparison, the rectal cancer excess is at least partly an artifact."

A The most appropriate basis for comparison for the deaths observed in the two plants looked at by Brown and Jones would have been the deaths of the rest of the population in the area immediately surrounding the plant.

Brown and Jones in fact compared that mortality to the United States as a whole. The result of this was that in the area surrounding the plant, the background mortality for rectal cancer was higher than in the United States; therefore, if they used the area around the plant, the number of expected deaths from rectal cancer would have been higher, and since their judgment of excess was based on the number of observed deaths compared to the expected deaths, if they used the local area, the number of expected deaths would have been larger.

So the excess which was not statistically significant in any way would have been smaller or perhaps

nonexistent.

Q On the bottom of Page 19 and the top of Page 20, you discuss the Bertazzistudy and state that:

"In spite of the statistical significance of the excesses from all cancers, this study must be considered a preliminary report, particularly since it shares with the other studies, a failure to agree on any particular pattern of mortality."

Can you tell me what you mean there by it shares with the other studies, a failure to agree on any particular pattern of mortality?

A Yes. This is the criterion that I mentioned that in order to infer carcinogenicity, the results must be repeatable in independent studies.

Here we have a group of studies including Bertazzi, and in each case there is excess generally non-significant, but the most important thing is every study shows an excess from a certain cause. The other studies will show either a deficit or complete absence of death from those causes. If the studies had shown excesses from the same causes or a group of causes that overlapped, one would have said that it might be reasonable to suspect carcinogenicity, but in fact each and every study neatly disagrees with each other.

For example, the excesses found by Zack and Musch is entirely absent in Bertazzi's study. There is a deficit of the lung cancer in the Brown study. The excess of liver cancer found in the Brown study is absent entirely from the Bertazzi study and so you see, none of these studies shows an excess in common with any other study.

Q Because of that lack of consistency, that is the basis for your conclusion that PCBs are not carcinogenic?

A That is, yes, that is the basis.

Q Is there any other component that forms the basis for that opinion?

A Yes. It is really part of the issue of consistency, but it is that even if the lack of consistency occurs, not only that there are different causes that are in excess but that the excess in one study is different than in another; not that it is just that much of an excess. It is not that we have something approaching statistical significance, but not above the maximum number.

As you go from one study to another, these numbers disappear. There is not an excess of them, so it isn't as if each study, that these almost

reach a significance. It is completely random in these studies and that they find excesses is essentially the basis of my judgment.

MS. STEIN: I don't have any other questions.

MS. OLIVER: I have no questions.

MR. FEATHERSTONE: I have two.

CROSS EXAMINATION

BY MR. FEATHERSTONE:

Q Dr. Gaffey, Exhibit 2 to your deposition is an article entitled The Epidemiology of PCBs, dated September 15, 1981.

In connection with the preparation of that paper, did you review the articles listed in Exhibit 3 to your deposition with the exception of the article authored by Chase, et al.?

A Yes.

Q Was Gaffey Exhibit No. 2 to your report and the review of your literature that went along with it done in preparation for litigation?

A No. As I testified earlier, it was done in preparation for a presentation to the American Medical Society about a year and a half ago as a result of a request from the organizing committee of that Society's annual meeting.

Q Were you asked to be a witness in this litigation after you had completed your preparation of your report and your review of the literature?

A It was after I had completed it and after I had presented it.

Q Dr. Gaffey, you were asked some questions by Ms. Stein as to whether you had an opinion about the risk to human health to a person walking around the area of the OMC facility in Waukegan Harbor.

In response to her question, you responded that you had no opinion?

A That's right. I have no information as to the actual exposure of those persons.

MR. FEATHERSTONE: I have no further questions.

Ms. Stein?

MS. STEIN: Nothing.

MR. FEATHERSTONE: Signature before any notary as we usually do.

(Witness excused.)

FURTHER DEPONENT SAYETH NOT. . .

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

THE UNITED STATES OF AMERICA,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	No. 78 C 1004
	)	
OUTBOARD MARINE CORPORATION and MONSANTO COMPANY,	)	
	)	
	)	
Defendants.	)	

I hereby certify that I have read the foregoing transcript of my deposition given at the time and place aforesaid, consisting of Pages 1 to 156, inclusive, and I do again subscribe and make oath that the same is a true, correct and complete transcript of my deposition so given as aforesaid, as it now appears.

_____
William R. Gaffey

Subscribed and sworn to
before me this _____ day
of _____, A.D. 1982.

_____
Notary Public.

Theo L. Urban
Certified Shorthand Reporter
134 South La Salle Street
Chicago, Illinois 60603
312 - 782-3332

UNITED STATES OF AMERICA)
NORTHERN DISTRICT OF ILLINOIS)
EASTERN DIVISION) SS:
STATE OF ILLINOIS)
COUNTY OF COOK)

I, Thea L. Urban, a notary public in and for the County of Cook and State of Illinois, do hereby certify that WILLIAM R. GAFFEY was by me first duly sworn to testify the whole truth and that the above deposition was recorded stenographically by me and was reduced to typewriting under my personal direction, and that the said deposition constitutes a true record of the testimony given by said witness.

I further certify that the reading and signing of said deposition was not waived by the witness and his counsel.

I further certify that I am not a relative or employee or attorney or counsel of any of the parties, or a relative or employee of such attorney or counsel, or financially interested directly or indirectly in this action.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my seal of office at Chicago, Illinois, this ________ day of June, A.D. 1982.

____
Notary Public, Cook County, Illinois.
My commission expires May 31, 1983.

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Curriculum Vitae of

William R. Gaffey, Ph.D.

Born: February 10, 1924, Jersey City, New Jersey

Education: University of California (Berkeley), 1948 A.B. (Psychology)

University of California (Berkeley), 1955 Ph.D. (Mathematical Statistics)

Professional Positions Held:

Assistant Professor of Biostatistics, University of California School of Public Health, Berkeley, 1955-1960

Statistical Consultant, California State Department of Public Health, 1960-1968

Chief, Bureau of Statistical Services, California State Department of Public Health, 1968-1969

Senior Biostatistical Consultant, Pacific Medical Center, 1970-1971

Associate Director, Human Population Laboratory for Epidemiologic Studies, California State Department of Public Health, 1971-1972

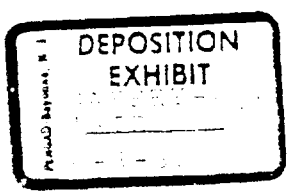
Director, Health and Epidemiological Studies, Tabershaw/Cooper Associates, Inc., 1972-1976

Senior Epidemiologist, Stanford Research Institute, 1976-1979

Manager, Epidemiology, Monsanto Company, 1979-Present

Lecturer in Biostatistics, U.C. School of Public Health, Berkeley, 1961-1979

Lecturer in Epidemiology and International Health, U.C. Medical School, San Francisco, 1964-1978



W. R. Gaffey, Ph.D.
Curriculum Vitae

Membership in Associations and Societies:

American Association for the Advancement of Science
American Public Health Association (Fellow)
American Statistical Association
Biometric Society
Institute of Mathematical Statistics
New York Academy of Sciences
Royal Society of Health
Society for Epidemiologic Research

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The Epidemiology of PCBs

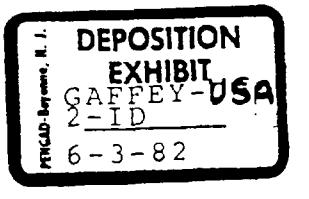
by William R. Gaffey

Monsanto Company

September 15, 1981

I. Summary

Twenty four published and unpublished reports covering 21 epidemiologic studies of human exposure to PCBs were reviewed and evaluated. The studies showed that high occupational exposures to PCBs have resulted in chloracne and dermatitis. Alterations in liver and fat metabolism were found in most studies that examined these functions, but there was no clinical illness associated with these alterations or with level and duration of exposure to PCBs. Studies of mortality rates in exposed populations have shown no pattern of cancer deaths related to PCB exposure.



II. Introduction

This is a review and evaluation of the epidemiologic evidence concerning the health effects of exposure to PCBs, particularly at levels that do not cause acute toxic effects. A study is considered "epidemiologic evidence" if it measures, directly or indirectly, the differences in the risk of ill health among populations with different exposures to PCBs.

In the past several decades there have been many clinical studies of the effects of heavy exposures to PCBs (e.g. Von Wedel et al [1], Schwartz [2]). Such studies are extremely useful in identifying the kinds of effects that should be investigated. However, they do not address the question of the risk of incurring such effects, and are therefore not included in this review.

The studies reviewed here fall into three categories. First, there are studies of accidental heavy exposures and the resulting acute and chronic effects. In each case the study was prompted by an outbreak of illness or the occurrence of a death in an exposed population, after which the population was studied.

Second, there are studies of the relationship between exposure to PCBs and the resulting body burden of PCBs in serum or adipose tissue. Strictly speaking these are not epidemiologic studies since they do not deal with health effects. However, if a relationship between level of exposure and body burden cannot be verified, the interpretation of epidemiologic studies becomes difficult if not impossible.

The third category is studies that were done because the populations in question were known or suspected to be exposed to PCBs, rather than because some untoward health outcome had been observed first.

Many published reports combine some or all of these types of investigations. In the sections that follow, we consider first the studies of accidental overexposure, second the studies of PCB exposure versus body burden, and third the epidemiologic studies of exposed populations. In the latter section the discussion will be organized with respect to the health effects that were investigated. These are (a) dermatologic symptoms (b) biochemical alterations, (c) other symptoms and illnesses, (d) carcinogenicity.

III. Accidental Heavy Exposures

Two epidemiologic studies of accidental exposure have been reported. The first, by Meigs et al [3] in 1954, described an outbreak of chloracne in a plant in which a process change had introduced an unspecified PCB compound into the work environment. Breathing zone levels of PCB were stated to be 0.1 mg/cum. Seven of 14 exposed workers developed chloracne, but liver function tests were normal in six of these, with some borderline abnormalities in the seventh. The chloracne disappeared after treatment, and the single borderline liver function abnormality improved, but did not disappear after 13 months. Improved process control prevented any recurrence.

Although the estimated PCB level must be accepted with reservation because of the state of the art at that time, it is clear that the chloracne resulted from the PCB exposure. Given the lack of controls and the small rate of abnormal liver function, it is unlikely that the PCB exposure had any connection with the liver function findings.

The second incident is the now famous Yusho incident in 1968 which has been documented in many reports (Kuratsune et al [4], Urabe et al [5]), in which some thousand Japanese became ill after eating cooking oil which had been contaminated with Kanechlor 400, a PCB compound of Japanese manufacture.

The most common acute symptoms observed were hyperpigmentation and acne-like lesions, discharge from the eyes, central nervous system symptoms, and vomiting and diarrhea. There was a

dose-response relationship between the amount of oil ingested and the proportion of persons reporting symptoms. Three years later about half the patients had improved, but still had symptoms. Six years later many patients still reported such symptoms as headache, stomach pain, numbness of the extremities, joint pain and respiratory symptoms [5].

Out of ten live births to women affected by Yusho, nine showed hyperpigmentation and most had increased eye discharges. These symptoms later disappeared. Although there have been reports of premature eruption of teeth (two children out of a series of 13) and unusually wide fontanelles and sagittal sutures (three out of 13) it is not at all clear that these findings represent any more than the normal variation to be expected, since no control observations were made (Funatsu et al [6]).

In general, laboratory tests of the Yusho victims showed elevated serum triglyceride levels, low serum chlolesterol in serious cases, and elevated SGOT and SGPT levels in serious cases (Higuchi [7]).

As of the end of 1977, 51 deaths among Yusho patients had been identified [5]. The percentage of cancer deaths (35.4) exceeded that of the prefecture in which the deaths occurred (21.1). However, the figures do not appear to be very useful for several reasons. First, after the original incident, the criteria for diagnosis of Yusho had been changed, so that it is impossible to determine the denominator which produced this number. The completeness of ascertainment of the deaths is unknown. In addition, no adjustment for age appeared to have been made in the

above comparison. Finally, the average elapsed time from exposure to death was less than ten years, and cannot be calculated precisely because the dates of death are not provided. This may well be too short a period for cancers resulting from the exposure to show up.

Although the Yusho incident represented a massive ingestion of PCBs, recent reanalysis of the cooking oil and of the estimated intake by the patients shows that the exposure to polychlorinated dibenzofurans (PCDFs) and polychlorinated quater-phenyls (PCQs) was about equal to the exposure to PCBs, and current determinations of PCQs in blood and other tissues of Yusho patients have shown levels similar to that of PCBs [8]. It is therefore doubtful whether any generalization can be made from this incident to lower level environmental or occupational exposures to PCBs.

IV. Environmental Levels and Body Burdens

Two studies of the relationship between ingestion of PCBs and blood levels of PCBs have been reported (Michigan Dept. of Public Health [9] and Kreiss et al [10]). In each case the study was concerned with ingestion of fish known to contain relatively high levels of PCBs. In the first, an association was found between blood PCBs and exposure level as estimated by the amount of Lake Michigan sport fish consumed. In the second the relationship between blood PCBs and a complex of factors was examined in a population in an area with high levels of environmental contamination. Age, sex and fish consumption, in that order of importance, were associated with blood levels of PCBs. To the extent that fish consumption measures ingestion of PCBs, these studies confirm that blood PCBs are a function of ingestion of PCBs as well as of age and sex. Other associated variables were examined in [10] but will be discussed in the following section.

A number of studies of blood PCBs and exposure to atmospheric PCBs have been made, most of them in conjunction with studies of health effects. The portions of the studies relevant to this section are reviewed here.

There are three types of studies. The first compares groups which have had different exposure levels as estimated from process considerations or environmental measurements. For convenience such a study design will be called Type A. The second, which we will designate Type B, measures the change over time in a single group after PCBs have been removed from the environment (or after

the group has left the environment). The third, Type C, compares groups that have had different durations of exposure. Often the same report will contain more than one type of study. For example, an exposed group may be compared with an unexposed group (Type A) and within the exposed group long term exposed workers may be compared with short term workers (Type C).

The measure of body burden has in most cases been a single number representing, depending on the study, blood PCBs, plasma PCBs, serum PCBs (all of which are called "blood" PCBs in this review), or level of PCBs in adipose tissue. Analytic methods have varied over time and among investigators. More recently measures of body burden have sought to determine separately the levels of higher chlorinated biphenyls (5 or more chlorine atoms per molecule) and lower chlorinated biphenyls.

Table 1 lists the studies considered in this section, with the type of design and whether or not separate determinations of higher and lower chlorinated biphenyls were made. All of the studies except Baker et al are occupational.

All of the Type A studies agree in showing a higher body burden of PCBs in populations with higher environmental exposure, except for one anomaly in Baker et al. There, persons exposed to sludge containing PCBs had slightly lower blood levels than the controls, on the average. However, the sludge exposed persons and the controls were not matched for age, which Kreiss et al showed to be the most important factor associated with blood PCB level. It therefore appears unequivocal that higher exposure to PCBs means a higher body burden, all other things being equal.

The Type B studies appear at first glance to be more equivocal (Table 2). Two studies show a decrease when exposure ceased or decreased and two do not. However, the studies showing no decrease remeasured their study groups within a month or two after exposure changed. The ones showing a decrease remeasured after three months and one year.

The fact that Ouw et al found no decrease after two months while Kitamura et al found over a 50 percent decrease after three months gives rise to some uneasiness. However, in the former study exposure was decreased but still present, while in the latter study PCB use had ceased. Ouw et al also suggest that after exposures in their study plant had decreased, workers did not wear gloves as recommended, so that the blood PCB levels may have resulted from skin contact.

Table 3 shows the findings for the Type C studies other than Maroni et al and Smith et al that is, for those that compared duration of exposure with a single measurement of blood PCB level. The results are not consistent. The study of Baumgarner et al found very low levels (average 4 ppb) in exposed workers, which may have accounted for their failure to find a relationship with duration. On the other hand the exposed workers in Hasegawa et al had an average level of 370 ppb and still showed no relationship with duration.

The studies of Maroni et al and Smith et al suggest a possible explanation. Maroni et al made separate comparisons of high chlorinated PCBs and low chlorinated PCBs between workers with present and past exposures. They found differences in the

low chlorinated PCBs but not in the high chlorinated compounds. Even though their analysis did not adjust for age, it suggests that the relationship between blood PCB levels and duration and recency of exposure may be a function of the level of chlorination of the PCBs. Smith et al however, in an elaborate analysis of high and low chlorinated blood PCBs versus present and past exposure, found no "evidence either to support or refute different accumulation kinetics in humans for the lower and higher chlorinated biphenyls". Nevertheless, they found a significant correlation between current personal air PCB levels and low chlorinated blood PCBs, but no significant correlation with high chlorinated blood PCBs.

In summary, body burdens of PCBs are clearly related to the level of exposure to environmental PCBs. Observations of a decrease in the burden of PCBs after exposure is eliminated or decreased are not consistent. The lack of consistency may be due to the short periods of observation of some of the studies, or possibly to differences in the average chlorination of the PCBs involved. Studies of the relationship of PCB burden to duration of exposure again are not consistent. There is a suggestion that this may be due to the confounding effects of age and sex, or to differences in the metabolism of high and low chlorinated PCBs, with the higher PCBs being more likely to accumulate in adipose tissue.

V. Epidemiologic Studies of PCBs and Health

Excluding mortality studies, there are 17 epidemiologic studies of health effects related to PCB exposure. The accident report of Meigs et al is included since it did not differ in design from many of the studies that were not motivated by accident reports.

These studies are listed in Table 4 with a summary of the findings by major category. Five of the reports are in Japanese [13,14,15,16,18]. The details of those studies are taken from the NIOSH criteria document for PCBs [34].

Two of the studies, Kappanen and Kolhol and South Carolina Department of Health and Environmental Control are not specific as to health effects. The first of these is a comparison of groups with different work exposures and different blood PCB levels (74-1900 ppb in the 12 persons with the greatest exposure) in which the authors simply state that all persons studied were in good health. The second is a study of 32 workers in a capacitor plant, 10 of whom were exposed regularly to PCBs. The authors state that there is "no evidence of physical harm resulting from working with PCBs".

The remaining 15 studies in Table 4 are reviewed below with respect to their findings in each major category of health effects. The studies are considered in the order of their publication.

Dermatologic effects. There are 11 studies of dermatologic effects associated with PCB exposure. The first is Meigs et al

described in Section II above, who found that 7 of 14 exposed workers got chloracne where the PCB concentration in their breathing zones averaged 0.1 mg/cum. Hasegawa et al reported an unstated number of cases of hyperpigmentation of the hands, and acne-like lesions of the jaw, back and thighs in exposed workers. The average blood PCBs in the workers was 370 ppb. However, the authors state that skin complaints were unrelated to blood PCB levels and appeared to be due to skin contact. Kitamura et al reported a range of skin disorders in 10 of 13 exposed workers with an average blood level of 820 ppb. The disorders occurred on parts of the body not normally in direct contact with PCBs. Hara et al reported that about 45 percent of 118 capacitor workers complained of blackheads and other acne-like symptoms while working with PCBs. The complaints were not related to blood levels of PCBs, and virtually disappeared within a year after exposure had ceased.

Inoue et al reported one case of chloracne in an exposed worker whose blood PCBs were in the 190-210 ppb range, but no symptoms in the rest of a small work force whose blood PCBs ranged from 130 to 520 ppb. The Michigan Department of Public Health reported no relationship of any Yusho symptoms to consumption of fish with high levels of PCBs. Ouw et al reported 14 cases of dermatitis, eye irritation or burning sensations on the skin out of 34 exposed workers, where air levels of PCBs ranged from 0.32 to 2.22 mg/cum. The complaints appeared to occur more often in those with higher blood PCB levels. Fischbein et al reported that about 50 percent of 326 capacitor manufacturing workers reported a

history of dermatological symptoms, the most common symptom being a rash. Those with symptoms had higher blood levels of high chlorinated PCBs. Baker et al reported no chloracne in 18 exposed workers (average blood PCBs 75.1 ppb) or 19 members of their families (average blood PCBs 33.6 ppb). Maroni et al reported 10 cases of dermatitis (5 diagnosed as active or past chloracne) out of 80 exposed workers. The average blood PCB level in the study was 342 ppb. Smith et al found no chloracne in a study population of 324 exposed workers in capacitor manufacturing and transformer repair, whose average blood PCBs ranged from 38 to 546 ppb. However, there was a significant association of skin rash or dermatitis with blood levels of high chlorinated PCBs.

Interpretation of this mass of data is complicated by the difficulty of diagnosing chloracne, the uncertainties of blood PCB determinations, and the changing technology for making such determinations. Nevertheless, the data suggest strongly that when PCB blood levels exceed about 150-200 ppb chloracne can occur. However, most studies have shown that the occurrence of chloracne is not further associated with blood PCB levels. This suggests that (a) personal idiosyncratic factors may be involved and/or (b) that the high blood levels are an indicator of the existence of environmental contamination which actually produces chloracne by skin contact.

The reports of dermatitis other than chloracne suffer from an additional complication. According to the National Health Survey, about one-third of all Americans of working age have at least one current skin condition serious enough to warrant evaluation by a

physician [25]. Clearly, substantially more than one-third must have either a current condition or a history of such a condition in the past. The prevalence figures reported by Maroni et al and Fischbein et al are therefore not in themselves remarkable, but the agreement of Fischbein et al and Smith et al on the relationship between dermatitis and high chlorinated blood PCBs suggests that this association may be real.

Liver Function. Nine studies examined liver function. Meigs et al found one borderline abnormal liver function in 14 exposed workers. Hasegawa et al found mild disturbances in exposed workers (increased SGOT, SGPT, SAP, decreased serum cholinesterase) which they did not consider to be clinically significant. Ouw et al, Kitamura et al, Fischbein et al and Baker et al (a non-occupational study) found no abnormalities associated with exposure, except that Ouw et al found a high BSP retention in 4 out of 7 workers with blood levels above 500 ppb.

Maroni et al found 16 out of 80 workers with abnormalities in GGT, OCT and transaminases. Their blood PCB levels were higher than those in the workers with normal liver function. Kreiss et al (non-occupational study) found no relation between liver function and blood PCBs when age and alcohol consumption were taken into account. Smith et al found elevated SGOT and GGT levels in persons with higher blood PCB levels.

In summary, 5 studies of the 9 found some mild liver function abnormalities, none of which were associated with any measurable adverse health effects. The two non-occupational studies, Baker et al and Kreiss et al, found no abnormalities associated with

blood PCB level. Fischbein et al, in their study of capacitor manufacturing workers, noted that "there was a paucity of abnormal results in the biochemical studies".

Fat Metabolism. Six studies considered fat metabolism. One, Bumgarner et al, found no relationship between blood cholesterol and blood PCBs. One of the remaining 5, Hasegawa et al, found a decrease in cholesterol, glycerides, phospholipids and beta-lipoprotein in exposed workers. Of the remaining 4, Hara et al, Baker et al (non-occupational study), and Smith et al found increased triglyeride levels with increased blood PCBs. Kreiss et al found no association of triglycerides and blood PCBs when cholesterol level was taken into account. Smith et al and Kreiss et al also present contradictory findings with respect to HDL cholesterol levels; the former found an inverse relationship of HDL to blood PCBs; the latter found no relationship, but found a positive association between total cholesterol and blood PCBs.

Most studies, including one non-occupational study (Baker et al) have associated increased tryglycerides with PCB exposure. The data on cholesterol are not consistent; an increase, a decrease and no change were found (one study each). HDL cholesterol either decreased or was unchanged (one study each). Even if PCB exposure has some effect on fat metabolism, it appears to be without any apparent clinical significance.

Blood and Blood Pressure. There are five studies of blood chemistry; Bumgarner et al, Kitamura et al, Fischbein et al, Baker et al, and Maroni et al. None of them report any relationship of blood chemistry to PCB levels.

Bumgarner et al and Kreiss et al measured blood pressure in exposed persons. Bumgarner et al found no association with PCBs, but Kreiss et al found a statistically significant association between diastolic blood pressure and blood PCBs. Since there was no control group and since Kreiss et al are the only investigators to report this finding, its significance is not clear at this time.

Symptoms, Illness and Other Conditions. Six studies investigated reported symptoms in persons exposed to PCBs. Two of them reported allegedly increased symptoms of various kinds. Fischbein et al reported a history of gastrointestinal symptoms in 18 percent of 326 capacitor manufacturing workers, a prevalence of from 3.0 to 15.2 percent of various musculoskeletal symptoms, and a prevalence of from 4.8 to 27.8 of various neurological symptoms. These were, however, unrelated to duration of employment or to level of blood PCBs. Maroni et al reported 8 cases of gastrointestinal complaints in 80 exposed workers, with no indication of whether there was a relationship to duration of employment. They also reported two bleeding haemangiomas and one case of chronic myelocytic leukemia. These findings do not appear to have any significance, since they apparently are unrelated to the circumstances of exposure, and since the following 4 studies reported no symptoms related to PCBs.

The Michigan Department of Public Health compared a group of persons who consumed sport fish contaminated with PCBs to a group of unexposed controls. The incidence of 18 conditions, many of them the ones reported for Yusho disease, was measured in the two

groups. There were no health conditions that could be correlated with blood PCB levels or fish consumption. Baker et al reported that none of the following conditions were associated with blood PCB levels in a community study; fever, weight loss, anorexia, fatigue, headache, eye irritation, cough, shortness of breath, nausea, vomiting, diarrhea, abdominal pain, arthralgia, and persistent skin rash. The community study of Kreiss et al reported the same thing for prevalence of illness or weight loss in the preceding year, use of medication, use of medical care, history of heart disease, and percentage of pregnancies ending in miscarriage, stillbirth or infant death. Finally, Smith et al reported an increased prevalence of general malaise and possibly altered peripheral sensation with increased blood PCB levels among occupationally exposed workers, but found no clinical abnormalities on physical examination.

The weight of evidence, as Smith et al conclude, is that no studies to date "have shown that occupational exposure to PCBs is associated with any adverse health outcome, to be distinguished from demonstrable subclinical biochemical alterations".

Two studies considered other conditions in persons exposed to PCBs. Warshaw et al reported decreased vital capacity in capacitor manufacturing workers. However, the pulmonary function values in the study population, most of whom were current or ex-smokers, were evaluated in comparison with a standard population of non-smokers, so that the effect of smoking as a confounder was not allowed for.

Alvares et al reported that in 5 workers occupationally exposed to PCBs, the rate of drug metabolism was significantly higher than in a group of controls matched for age, sex, and smoking and drinking habits.

There appear to be no significant clinical effects associated with the occupational or environmental exposures studied in these reports.

Carcinogenicity. It is generally agreed that epidemiologic evidence for carcinogenicity should fulfill certain requirements in order to be acceptable. These requirements deal with the study design, the logic of the observed pattern, and the repeatibility of the results. Table 5 lists these requirements as given by Doll [28].

There are four studies directed solely or primarily to the question of the carcinogenicity of PCBs. Table 6 lists the studies and their findings. They are reviewed here keeping in mind Doll's requirements.

The most obvious feature of Table 6 is that no study agrees with any other. That is, the requirement of repeatibility is not met.

The first study, by Bahn et al, observed three melanomas in a group of 92 research and development and refinery workers. These workers had an unknown exposure to other possible carcinogens, so that there could have been confounding. In any case the study was withdrawn for revision in the definition of the exposed population, and has not yet been released [34].

Zack and Musch studied 89 workers exposed for at least six months between 1945 and 1965 inclusive. There were no deaths from cancer of the liver or cirrhosis. The excess in respiratory cancer was based on four deaths and was not statistically significant. As with Bahn et al there was confounding because of other chemical exposure at the plant and, in this case, possibly cigarette smoking.

Brown and Jones studied 2,567 workers in a capacitor plant. About half the cohort had a latency period of 20 years or more. Although there was an excess of liver cancer deaths, it was inversely related to duration and latency of exposure, which does not support an occupational explanation. There was also an excess of rectal cancer. However, the two plants studied are located in an area whose mortality from rectal cancer is greater than the U.S. average [35]. Since U.S. population rates were used as a basis for comparison, the rectal cancer excess is at least partly an artifact.

Bertazzi et al studied 1,310 workers with at least six months employment in capacitor manufacturing between 1946 and 1970. Although excess digestive cancer was observed, there were no liver cancer deaths. The total number of deaths was small (27) and the excess cancer observed was based on two or three deaths for each of the two major sites involved. There is no indication of the duration or latency of exposure for the cancer deaths. The authors state that there were no other major exposures at the plant, and propose to continue the study with a larger cohort. In spite of the statistical significance of the excesses from all

cancers, this study must be considered a preliminary report, particularly since it shares with the other studies a failure to agree on any particular pattern of mortality.

The existing mortality studies of occupational exposure do not show the agreement that would lead one to infer an excess risk of cancer. Much of the conflicting findings can be attributed to the possible effect of confounding exposures, and to the "noise level" of sporadic excesses which would be expected in the absence of any occupational hazard.

VI. Summary and Conclusions

The epidemiologic studies of exposure to PCBs show that the body burden in exposed persons, whether the exposure is by ingestion, inhalation or skin contact, is related to the environmental levels and distribution of PCB. The relation of body burden to duration of exposure is less clear, and appears to differ depending on the degree of chlorination of the PCBs. Nevertheless, the evidence is clear that higher exposures mean higher blood PCB levels, and that persons with occupational exposures have blood PCB levels that may be an order of magnitude greater than that of environmentally (that is, non-occupationally) exposed persons.

Occupational exposure to PCBs at high levels has been associated with the occurrence of chloracne, but the relationship is not straightforward, suggesting that the actual risk of chloracne is also a function of individual susceptibility and personal work habits, as well as possible exposure to other contaminants.

Dermatologic problems other than chloracne are associated with occupational exposure, and may be related to exposure to high chlorinated PCBs.

Alterations of liver function and fat metabolism associated with PCB exposure have been observed in several studies, but are characterized by investigators as mild and of no clinical significance.

The one fact on which all occupational studies of health effects agree is that there has been no clinical illness associated with PCB exposure other than dermatitis. Studies of non-occupationally exposed populations have found neither dermatitis nor other clinical evidence of exposure-related effects, with the exception of a single study which suggests that diastolic blood pressure may be related to blood level of PCBs.

Mortality studies concerned primarily with cancer present problems of interpretation due to the small sample size of some of the studies, and to the confounding effect of other exposures. However, they do exhibit a pattern, which is that none of the studies agree on the cancer sites at which an excess mortality was found, and the excesses that were found are in general not statistically significant. One must conclude that the findings of the mortality studies reflect a sporadic pattern of excess mortality at different sites which is not consistent with a carcinogenic effect of PCBS. In addition, where an examination of duration and latency of exposure was possible, no association with these variables was found [32].

Taken as a whole, the epidemiologic studies find that high occupational exposures to PCBs may cause dermatitis of various kinds, but that there are no other clinically observable effects, including the occurrence of cancer.

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Table 1

Studies of Environmental Levels and Body Burden of PCBs by Type of Body Burden Measure

Study	Study Type*	High & Low Chlorinated PCBs	Adipose PCBs
Baker, E et al [11]	A	No	No
Bumgarner, JE et al [12]	C	No	No
Hara, I et al [13,14]	B,C	No	No
Hasegawa, H et al [15]	A,B,C	No	No
Inoue, Y et al [16]	A,C	No	No
Karppanen, E, Kolho, L [17]	A	No	Yes
Kitamura, M et al [18]	B	No	No
Maroni, M et al [19]	A,C	Yes	No
Ouw, HK et al [20]	A,B	Yes	No
Smith, AB et al [21]	A,C	Yes	No

* A = comparisons of groups with different exposure levels
  B = evaluation of results of decreasing or removing exposure
  C = comparisons of groups with different durations of exposure.

Table 1

Studies of Environmental Levels and Body Burden of PCBs by Type of Body Burden Measure

Study	Study Type*	High & Low Chlorinated PCBs	Adipose PCBs
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Bumgarner, JE et al [12]	C	No	No
Hara, I et al [13,14]	B,C	No	No
Hasegawa, H et al [15]	A,B,C	No	No
Inc , Y et al [16]	A,C	No	No
Karppanen, E, Kolho, L [17]	A	No	Yes
Kitamura, M et al [18]	B	No	No
Maroni, M et al [19]	A,C	Yes	No
Ouw, HK et al [20]	A,B	Yes	No
Smith, AB et al [21]	A,C	Yes	No

* A = comparisons of groups with different exposure levels

B = evaluation of results of decreasing or removing exposure

C = comparisons of groups with different durations of exposure.

Table 2

Studies of Blood PCB Levels Before and After Exposure Levels Changed, and Interval from Exposure Change to Remeasurement

Study	Exposure Change	Interval to Remeasurement	Decrease in Blood PCB Level
Hara et al [13,14]	Ceased	1 year	~75%
Hasegawa et al [15]	Ceased	1 month	None
Kitamura et al [18]	Ceased	3 months	>50%
Ouw et al [20]	Decreased	2 months	None

Table 3

Studies of PCB Levels by Duration of Exposure

Study	Relationship of Blood PCB to		
	Duration of Exposure	Age	Race
Bumgarner et al [12]	No	No	No
Hara et al [13,14]	Yes		
Hasegawa et al [15]	No		
Inoue et al [16]	Yes		

Table 4

PCB Epidemiology Studies (other than mortality) and Summary of Findings*

	Dermatologic Findings	Physiological Parameters	Symptoms and Illness	Other
Alvares et al [27]		Y		
Baker et al [11]	N	Y	N	
Bumgarner et al [12]		N		
Fischbein et al [23]	Y	Y	Y	
Hara et al [13,14]	Y	Y		
Hasegawa et al [15]	Y	Y		
Inoue et al [16]	Y			
Karppanen, Kolho [17]				N
Kitamura et al [18]	Y	N		
Kreiss et al [10]		Y	N	N
Maroni et al [24]	Y	Y	Y	
Meigs et al [3]	Y	Y		
Michigan Dept of Public Health [9]	N		N	
Ouw et al [20]	Y	N		
Smith et al [21]	N	Y	Y	
South Carolina Dept. of Health and Environmental Control [22]				N
Warshaw et al [26]		Y		Y

* Y = Findings associated with exposure
N = No findings associated with exposure
No entry = No data presented

Table 5

REQUIREMENTS FOR ESTABLISHING CARCINOGENICITY FROM EPIDEMIOLOGICAL EVIDENCE

- Positive associations in groups of individuals with known exposure (case-control or cohort studies).
- That are not explained by bias in recording or detection.
- That are not explained by confounding.
- That are not explained by chance.
- That vary appropriately with dose.
- That vary appropriately with period of exposure.
- That are observed repeatedly in different circumstances.

Table 6

Inconsistencies in Studies of Cancer in PCB Exposed Populations, with Findings

Study	No. Studied	Findings
Bahn et al [29,30]	92	Melanoma**
Zack, Musch [31]	89	Lung
Brown, Jones [32]	2,567	Liver Rectum
Bertazzi et al [33]	1,310	Digestive* Lymphatic and hematopoietic

* Significant at 5 percent level

** Significant at 1 percent level

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06-17-82

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. OUTBOARD MARINE CORPORATION, Defendant, Third-Party Plaintiff, and Cross-Claim Defendant, and MONSANTO COMPANY, Defendant, Third-Party Defendant, and Cross-Claim Plaintiff.	Civil Action No. 78 C 1004 Honorable Susan Getzendanner

NOTICE OF FILING

TO: All counsel on attached
Service List

PLEASE TAKE NOTICE that we have this date filed DEFENDANT MONSANTO COMPANY'S THIRD SET OF REQUESTS FOR ADMISSION TO PLAINTIFF UNITED STATES, a true copy of which is attached hereto and served upon you.

This 17th day of June, 1982.

Fred H. Bartlit, Jr.
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Attorneys for MONSANTO COMPANY

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IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. OUTBOARD MARINE CORPORATION, Defendant, Third-Party Plaintiff, and Cross-Claim Defendant, and MONSANTO COMPANY, Defendant, Third-Party Defendant, and Cross-Claim Plaintiff.	)	Civil Action No. 78 C 1004 Honorable Susan Getzendanner

DEFENDANT MONSANTO COMPANY'S THIRD SET OF
REQUESTS FOR ADMISSION TO PLAINTIFF UNITED STATES

In accordance with Rule 36 of the Federal Rules of Civil Procedure, defendant Monsanto Company requests that plaintiff United States make the following admissions:

REQUESTS TO ADMIT

1. On October 28-29, 1981, the deposition of Dr. Wayland R. Swain was taken in Chicago, Illinois. Dr. Swain testified under oath.

2. At the time of his deposition, Dr. Swain was employed as chief of the United States EPA's Large Lakes Research Laboratory at Grosse Ile, Michigan. Dr. Swain was familiar with research regarding PCB levels in fish and human health effects of PCBs.

3. At his deposition, Dr. Swain was asked these questions and made these admissions (pp. 206-207):

"Q All right. Assuming first that the fish immediately outside of Waukegan Harbor have no different PCB levels than fish caught elsewhere in Lake Michigan --

A All right.

Q From that you have offered the opinion that those fish immediately outside of Waukegan Harbor spend little if any time in the waters of Waukegan Harbor.

* * *

Q Isn't that right, Doctor?

A No. In contact with the materials from the Harbor.

Q Why don't you give me the complete answer because you gave me a fragment of an answer and I don't understand what you mean.

A All right.

Fish to which you have reference did not spend or would not have spent time apparently in contact with the materials, PCB materials from Waukegan Harbor, either through the food chain or the water column uptake."

4. At his deposition, Dr. Swain was asked these questions and made these admissions (pp. 218-220):

"Q Dr. Swain, are you aware that PCB levels in Lake Michigan fish have declined substantially in recent years?

A There is evidence that indicates there has been a decline, yes.

Q Do you consider it a significant decline?

A Yes.

Q What is your explanation for the decline in PCB levels in Lake Michigan fish?

A My expectation would be that it was a function of the amount of loading to the Lake as a whole.

* * *

Q By that do you mean that the PCB inputs into Lake Michigan have decreased and thus the PCB levels in the fish have decreased?

A Yes.

Q Do you also attribute the decline in the PCB levels in Lake Michigan fish to the fact that PCBs have been buried in the sediments of Lake Michigan and have therefore dropped out of the food chain, if you will?

A That is one of the lost terms for the ecosystem as a whole. It is a normally functioning process within a body of water so that does constitute a removal process, yes.

Q On the basis of your review of information and the literature, Doctor, do you consider that burial of PCBs in the sediments of Lake Michigan and thus their removal from the food chain to be a substantial loss of PCBs from the system?

A Yes, it appears to be a principal loss mechanism.

* * *

Q Do you have any reason to believe that the declines in the PCB levels in Lake Michigan fish that have been demonstrated in the last few years will not continue in the future?

A Barring unusual consequences or unforeseen consequences, I have no reason to believe they will not continue to decline."

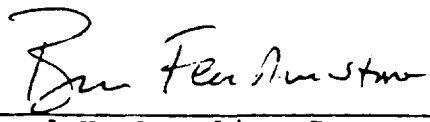
5. At his deposition, Dr. Swain was asked this question and made this admission (p. 256):

"Q On the basis of what you know today and what you have medical confidence in, do you agree with this statement:

> 'The fact remains that after more than 30 years of widespread environmental exposure to PCBs, we have no documented case histories of human injury or poisoning due to chronic trace exposure to these chemicals'?

A Within the context of the question as you framed it, I would have to be forced to agree with the statement."

DATED: June 17, 1982



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CERTIFICATE OF SERVICE

BRUCE A. FEATHERSTONE hereby certifies that on June 17, 1982, he caused a copy of DEFENDANT MONSANTO COMPANY'S THIRD SET OF REQUESTS FOR ADMISSION TO PLAINTIFF UNITED STATES to be hand delivered, by messenger, to all counsel on the attached Service List.

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